THE TRIPS AGREEMENT – TEN YEARS LATER

A Report of a Conference Commemorating the 10th Anniversary of the TRIPS Agreement held on 23rd and 24th June 2004

European Commission, DG Trade

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Executive Summary

This year marks the tenth anniversary of the conclusion of the Marrakesh Agreement establishing the World Trade Organisation. One of the most innovative aspects of this global trade agreement was the Agreement on Trade-Related Aspects of Intellectual Property Rights. Its conclusion laid the basis for a truly globalised intellectual property regime. At the same time, its implementation led to the emergence of important political debates in the WTO, notably on the impact of intellectual property on the developing world, access to medicines, and the protection of geographical indications. These debates are a reflection of the challenges of the global trading system regulated by the WTO.

The conference reported here was hosted by DG Trade of the European Commission in order to look back at these ten years and, more importantly, to examine the prospects for the future. The event brought together influential actors – from industrialists to governmental representatives, international organisations, NGOs and academics – with an interest in intellectual property worldwide. The aim is to assess from the widest possible number of perspectives the implications of the TRIPS Agreement and future trends and challenges in global intellectual property protection.

The conference aimed to offer a high profile platform to address the key issues, such as the implications of the TRIPS Agreement for developing countries, enforcement challenges, the interplay between intellectual property and human rights, the relationship between intellectual property and the public domain and the question of whether the TRIPS Agreement is adequate to the challenges of globalisation and the knowledge society.

The conference also examined issues which are not only of direct relevance to the global trading system, including the negotiations in the WTO under the Doha Development Agenda, but also to substantial development, transfer of technology and research and development.

The event consisted of four panels, each with high profile speakers, who engaged in open debate. The speakers on each panel were asked to address a number of key questions. These key questions were:

Panel 1: Ten Years of the TRIPS Agreement: Taking Stock

- What has been the effect of globalising intellectual property rights?
- Has the TRIPS Agreement lived up to expectations?
- Have developing countries experienced TRIPS as an obstacle or a booster for development?
- What types of problems have been experienced in the implementation of TRIPS?
- Have solutions been adequate?

Panel 2: Enforcement Challenges

- What are the strengths and weaknesses of the enforcement mechanisms in the TRIPS Agreement?
- How should piracy and counterfeiting be tackled?
- What are the costs of non-implementation of TRIPS vs. the cost of implementation of TRIPS?
- Is IP enforcement really a priority for developing countries?
- Is it time for a new strategy for enforcement of intellectual property rights?

Panel 3: IPRs, Human Rights and the Public Domain

- Are there conflicts between IPRs and Human Rights?
- Are intellectual property rights marginalizing the public domain?
- Do IPRs on biotechnology lead to privatisation of life and natural resources?
- Are IPRs and the knowledge society friends or foes?
- Intellectual property rights and research: is the tool serving its purpose?

Panel 4: Outlook for the future of TRIPS: How to ensure an appropriate IPR system in a globalised economy?

- Is the TRIPS Agreement adequate to respond to the challenges of the knowledge society?
- Is there a need for restoring the freedom of developing countries to adopt systems they consider best to advance their economic and social development needs?
- How do we take account of diverse collective preferences?
- Is the TRIPS Agreement sufficiently flexible?
- Is further harmonisation of IP rules a viable option?
- Future trends?

Opening Address by Pascal Lamy, EU Trade Commissioner

Pascal Lamy welcomed participants to the conference, which he said that he was hosting on almost exactly the 10th anniversary of the TRIPS Agreement.

In the past, intellectual property was often seen as an obscure speciality – the sole preserve of lawyers. This has now changed, with intellectual property rights now something of a hot topic for debate. Within the European Union, many issues which at first sight may seem unconnected have provoked heated discussion: biotechnological inventions (such as GMOs, genetic resources, and DNA), access to medicines, geographical indications, software, dissemination and access to the internet, to name but a few.

All these issues have revealed widespread public concern and raised difficult political, societal and sometimes ethical questions for policy makers. There is a need to address these questions head on.

But are these new questions? We live in times where skills, knowledge and technology have become decisive assets in a global competitive economy. Today, access to technology and the distribution of knowledge are probably more important than the control of resources. They increasingly make the difference between economic success and failure. As a result, intellectual property has emerged as a truly key asset in ensuring technical advancement, growth and competitiveness.

So, we need to look at intellectual property with a fresh eye. We must take stock of our experiences to date, and assess the main challenges and questions ahead.

Pascal Lamy then said that he wanted to kick off discussions at the conference by broadly sketching out the international debate around intellectual property as he sees it today.

Intellectual property has become a global political issue

First of all, we should remember that intellectual property is a modern word for an old concept. Licences, copyright, and so on are rights that were invented long ago by national legislators. Some say the oldest trademark was issued by a Bavarian brewery in the 1030s. The first patent law dates back to the 1620s in the UK. The first copyright law was passed at the beginning of the 18th century, also in the UK. International agreements on intellectual property rights are also a long-established tradition, such as the Paris Convention of 1883 on industrial property and the Berne Convention of 1886 on copyrights.

So, protection of intellectual property developed in industrialised countries by gradually expanding its scope and range. But, throughout, one feature remained constant: policy makers have always had to strike a balance between creating incentives for innovation through private rights and serving society's interest in the dissemination of knowledge through the limitation of

these private rights. As intellectual property is a privatisation, albeit temporary, of knowledge in order to reward innovation, the key debate is about how to get this balance right. It is here that we must begin with our consideration of the TRIPS Agreement.

So why was the TRIPS Agreement concluded? Even during the Uruguay Round negotiations, it was evident that the future would bring an increasingly globalised 'knowledge economy'. This meant that competition in trade would focus increasingly on the quality and design of products and services rather than simply on the commodities themselves. Hence the need to ensure fair competition within the trade remit through a global regime of IP rights.

The conclusion of the TRIPS Agreement in 1994 represented a drastic change in the international framework of intellectual property, in three respects. First, unlike previous agreements, TRIPS is part of a global trade organisation, the WTO. As a result, it is subject to the binding WTO dispute settlement system. Second, the scope of TRIPS covers nearly all types of IP rights: patents, trademarks, copyrights, geographical indications and so on. Third, it contains detailed rules on enforcement. So, in terms of dispute settlement, broad coverage, and detailed rules on enforcement, the ambitions of the TRIPS Agreement were high.

Since its initiation, the world has changed. TRIPS has become a global political issue. The reason is that the original ambition is facing a new reality with the same old question of how global IP rules, which are designed first and foremost as private rights, can be best shaped to facilitate economic development and social welfare for all. This is a question that all trade negotiators face. Today's trade is not just concerned with goods and services, but also with technological evolutions, social values, political choices and wide gaps of economic development between countries. Trade-related intellectual property is in this respect no different from other trade rules.

More specifically, there are two challenges for the future: first, delivering global public goods; and, second, responding to the demands of development.

Delivering global public goods

Optimal delivery of public goods cannot be achieved by the market alone because they are not tradable. They must, instead, be provided through collective-action mechanisms. However, their delivery relies increasingly on technology or knowledge, which is concentrated more and more in private hands. This is not a new issue, but its intensity increases when it becomes linked to ethical or policy concerns to sustainable development. Some examples illustrate this point.

First, in relation to access to medicines, while some people consider that patents on pharmaceuticals prevent access for all to the newest and most effective treatments, others point to the fact that, without patents, it is unlikely that any treatment would have been developed at all. On the other hand, we

have a moral obligation to provide health care while, on the other, we have to encourage innovation in the pharmaceutical sector.

The second example is in relation to the shrinking of the public domain and the technological race. In the European Union there has recently been an intense discussion on the internet and software. Some years ago the EU had a not dissimilar discussion about biotechnology patents. Will the same debate expand into the interconnection of our domestic legislation with the domestic laws of trading partners such as the United States?

In other words, while the scope of IP rights expands, innovation cycles are becoming shorter. Science and technology evolve so quickly that technologies are no longer up-to-date at the time when intellectual property rights expire. Is a knowledge-based society sustainable if 'public' knowledge is losing ground to 'protected' knowledge?

The third example is in relation to the emerging concept of collective IP rights. Accommodating the legitimate aspirations of some societies in order to keep their strong collective traditions within an established framework such as TRIPS is a worthwhile endeavour. To be more specific, there is a case to be made in favour of establishing some boundaries to patents on natural resources by biotechnology industries in order to protect and respect traditional knowledge of indigenous populations and, by the same token, the environment. It may be controversial, but the same logic applies to geographical indications for agri-food products. Here, Europeans believe that our agricultural model should be recognised in its diversity and long traditions. Our approach promotes the idea that geographical indications are collective rights, which should be recognised as such, rather than using traditional trademarks as some suggest.

These examples demonstrate that, without global rules, we cannot expect often-contradictory objectives to coexist and deliver an optimal result for society. These global rules must be established in a world where societal choices, political values, and collective preferences largely differ.

The demands of development

For developing countries, the question is not only access to technology, but also access to the newest technologies in order to catch up with the developed world. Most of these new or advanced technologies are protected by IPRs.

So what is the relationship between intellectual property and the development process? In general, it is fair to say that IP is good for development. But understanding of its exact role in the development process is incomplete and there is an urgent need for academic research in this area.

Economists do agree on one thing: for the larger and more advanced developing countries, intellectual property can act as a tool to attract foreign

investment and to bolster domestic innovation, provided it is accompanied by the right policies. Brazil, India and China are some examples of this in action.

For least developed countries, however, the benefits seem less certain. There is, for example, a clear risk of high short-term social costs as a result of acceding to large-scale new technologies. So what can be done to ensure that the TRIPS Agreement can be beneficial for the least developed countries as well?

Another key issue is: what is the attitude of developing countries towards the TRIPS Agreement? There is some resistance. While some argue that IPRs must be good for developing countries as they have been a force for good in the developed world, others believe that IP is intrinsically bad and that the fewer rights the better. We should not fall into this trap of over-simplification and should look seriously at the two main concerns of developing countries.

A major concern is technology transfer and this was a controversial issue in TRIPS negotiations. Ultimately, a deal between IPR and transfer of technology was key to an agreement. It is important to remember that developed countries committed to stimulating the transfer of technology to least developed countries. Those countries are reminding us of that commitment in the context of the Doha Round negotiations and developed countries must ask themselves whether sufficient efforts have been made here, and how to deliver.

Another concern is the implementation of TRIPS. This is a costly exercise for developing countries because of the legal, institutional and administrative enforcement procedures required. These requirements often stretch the capacities and resources of the least developed countries to the limit. All too often, resources have to be allocated in favour of much more pressing basic needs. This, in turn, creates resentment from competitors in industrialised countries, who regard the lack of IP protection as unfair competition. This suggests that there is a pressing case here for technical assistance and capacity building.

Ten years on: drawing lessons from experience

Ten years after its conclusion, the TRIPS Agreement has passed from infancy to maturity. We have seen the effects it has produced and we have listened to the debates it has triggered. It is certainly not too early to draw some tentative conclusions from the experiences made.

The first lesson is that IP is a means, not an end. IPRs are justified by their societal purpose. They constitute a public policy tool to encourage innovation and creativity. These are the ends, and the patents and copyrights granted to innovators and creators are the means to achieve it. But the hierarchy of ends and means does not end here. Indeed, the encouragement of innovation and creativity is itself serving higher purposes: economic, social and cultural development that should benefit all.

So, international intellectual property policy is a question of striking the right balance between private interests, their public policy objective (access to knowledge) and other public goods. Should this public/private bargain be struck in the same way in all WTO Members? Not necessarily. Here the level of development and the national public policy objectives come into play.

The second lesson is that IPR alone will not do the job. Intellectual property is only one contributor to innovation, growth and development. It cannot work in isolation. In this regard, there is a parallel with the EU's general approach to trade liberalisation. In the EU's view, trade liberalisation can be an essential tool for economic and social development, provided a number of conditions are met: namely, it must be accompanied by the appropriate national policies; and it must be monitored by international institutions through coherent action, i.e. global governance.

So IP can be a tool for development if it is embedded in an effective innovation policy and the right accompanying policies, both at national and international level. Many think along those lines: look at the explosion of interest in IP issues in fora previously not concerned with them. This evolution could form the embryo of a much-needed global governance on access to knowledge.

The third lesson is that interpretation of TRIPS must fit its purpose. In Seattle, in 1999, the EU pointed out that TRIPS was a flexible instrument. At that time, Europe was isolated. But, very soon, flexibility became the name of the game and the Doha Declaration on public health shows how such flexibility can solve a sensitive political debate.

But we have to look beyond TRIPS. It is important that key flexibilities in other policy areas are not undermined in other multilateral fora or as a result of bilateral trade agreements. There is concern about some of the free trade agreements recently adopted between industrialised countries and developing countries: some of their IP provisions go far beyond their level of development and reduce their options of making use of the TRIPS flexibilities.

The fourth lesson is: do not fear public debate. Global IP rule making has, in the past, been dominated by the developed world, its experts and its industries. Other stakeholders were under-represented. Since the TRIPS Agreement has come into force, this situation has gradually changed. Intergovernmental organisations like the WHO and civil society organisations are increasingly penetrating into the fora where IP standards are set. Their efforts to balance the interests of IP right holders against larger public interest goals have been increasingly successful with respect to issues like public health, biodiversity, traditional knowledge or plant genetic resources.

Nobody should fear its evolution, but there is still some way to go: lack of expertise and of organisational capacities in many developing countries still hamper their full and well-informed participation in negotiations. While the work of international organisations is generally appreciated, the role of non-governmental organisations and business lobbies remains controversial.

Good governance depends on the eventual emergence of a truly credible and legitimate institutional framework. That framework is, for the time being, incomplete.

The EU and TRIPS

With regard to the EU's own policy, what consequences can we draw from these lessons? In this respect, there are two guiding principles: first, not taking a dogmatic approach but balancing policy objectives; and, second, respecting international commitments, but minimising the costs for the weakest.

How does this translate into more political terms? First, it translates into mutual supportiveness between IP and other policy areas. No international agreement can be read and implemented in isolation. The TRIPS Agreement itself is very clear about its intentions to find a balance 'to the mutual advantage of producers and users to technological knowledge and in a manner conducive to social and economic welfare'.

So, when we face the apparent contradiction between the protection of intellectual property and other policy objectives, out attitude must be to search for mutual supportiveness rather than for primacy. This is the EU's guiding principle in the debates on access to medicines and biodiversity. In both cases, there is nothing to be gained by constructing a false opposition between intellectual property, which is essential for new drugs or 'green technologies', and access to care or the protection of biodiversity.

What if there is indeed some contradiction? The TRIPS Agreement, like any other piece of law, is not set in stone. International law must adapt to international evolutions. Do we go as far as contemplating adaptation of TRIPS? The answer is clearly yes, and this is what the EU is currently promoting for a number of issues in order to take account of new developments. The first is to ensure a positive interface between TRIPS and the Convention on Biodiversity. The second relates to geographical indications, and our wish to extend protection to agri-food products, not just wines and spirits.

Adaptation was also a factor in the access to medicines debate when it appeared that a problem could not be solved by existing flexibilities. On this point, it is a matter of concern that such adaptation is still causing second thoughts despite the commitments made last year. To the extent that the 30 June deadline agreed to integrate last year's agreement will probably not be met, that will affect the credibility of the whole WTO membership. This is all the more regrettable given that the Doha Declaration and the 30th August waiver do provide a legal basis to implement these instruments at domestic level. Why have no developing countries yet notified the need for generic drugs to the WTO? The European Commission will seek to help by proposing a regulation implementing these instruments into domestic rules.

The second broad principle of EU action is that adopted rules must be implemented, including by helping the weakest. The reason is that TRIPS contains detailed minimum standards of IPR enforcement in order to ensure that IP right holders can rely on efficient administrative and/or judicial procedures for upholding their rights. Adopting new IP legislation is one thing. But devising the right tools to make them effective is another. Although most WTO Members have adopted implementing legislation, the level of piracy and counterfeiting continues to increase every year and has taken on industrial proportions. This is a serious concern for the EU. The ever-increasing seizures at the EU's borders of counterfeit products show what is at stake. Some of these products (for example, fake medications, food, electrical appliances) are increasingly from businesses run by criminal organisations. This is unacceptable to everyone.

Why should developing countries care about enforcement? The reason is that piracy and counterfeiting concerns their consumers as well as ours. Developing countries should care about organised crime as much as the EU does. It is also a matter of international credibility which is essential in the long term. Putting in place the right rules will encourage domestic authors, inventors and investors and contribute to the development of these countries.

So, existing rules should be properly enforced. The Commission services have prepared a new strategy on enforcement of intellectual property protection in third countries. Some will accuse the EU of hypocrisy: preaching flexibility while pushing for WTO+ arrangements. In reality, there are two reasons why this is not the case. The first reason is that what the EU requires is that TRIPS be applied according to the rulebook. The second reason is that the EU is fully aware that implementation of TRIPS is resource-intensive and introduces procedures that were previously unknown in certain WTO Members - hence the EU's use of trade-related technical assistance in this area. The priority is not just to enable countries to implement TRIPS provisions, but also to raise their awareness of its implications and to help make optimal use of its flexibilities and to tailor the appropriate flanking policies.

Conclusion

The TRIPS Agreement is a very first component of an emerging system of global governance in the field of knowledge and technology, alongside other institutions dealing with development, trade, IP and technology transfer. However, there is still a large gulf between the stated objective of TRIPS, namely a world where everybody can benefit from innovation and knowledge, and the reality on the ground. Without well-developed global governance, a global regime of IPR will remain difficult to implement to the benefit of all.

Experience shows that IP law can evolve and must be driven by global public interest objectives. No global system of IP can work unless most governments worldwide agree to enforce it. Governments will only agree to this enforcement if they are convinced that it works in their interests, and this is an essential question of legitimacy. What is needed is a forward-looking debate

on an international IP system that supports development, is supportive to other public goods and is in line with modern technologies. The challenge is how to make sure that this instrument can be implemented by countries with differing interests, different levels of development and different experiences in managing IP systems.

In conclusion, Pascal Lamy said that this is broadly how he saw the challenge ahead and that this is why he wanted this conference to happen. He asked the conference to take stock, take a fresh and undogmatic look at both the IP system and the international system, and search for creative solutions.

Finally, Pascal Lamy ended with four questions:

1. In general, is the balance established in 1994 between right holders and users of intellectual property still valid 10 years later?
2. What would be the policy goals or the technological evolutions that would justify changes in this balance, or new concepts or approaches?
3. Is global governance in the field of technology and knowledge satisfactory? If not, how can we improve it?
4. What should we do to improve the ability of developing countries to take full advantage of intellectual property protection?

PANEL 1: TEN YEARS OF THE TRIPS AGREEMENT: TAKING STOCK

Moderator: Lars Anell, former Ambassador of Sweden to the WTO, Chairman of the Uruguay Round Negotiating Group

Adrian Otten, Director of IP Division, World Trade Organisation

Adrian Otten noted the emphasis on developmental aspects in the conference programme and stated his intention to focus his remarks on this. By accepting TRIPS, developing countries made a valuable contribution to the success of the Uruguay Round negotiations as a whole. Of course, there were already a number of multinational intellectual property conventions but, by the 1980s, it was clear that these rules were not protecting the interests of industrialised countries. In order to strike a balance, Article 7 of the TRIPS Agreement provides for flexibilities. Yet the debate as to whether the TRIPS Agreement achieves a proper balance remains controversial. It is imperfect on both sides, not being accepted by all developed countries as protecting all their interests, hence the recourse to bilateral, TRIPS-plus trade agreements.

For developing countries, three sets of issues are worthy of note. First, TRIPS and public health, an issue on which flexibilities have been clarified in the Doha Declaration of 14 November 2001 and the subsequent WTO Decision of 30 August 2003. What these developments have made clear is that the TRIPS Agreement should be interpreted in a pro public health way. The second set of issues for developing countries involves biotechnology, biodiversity, traditional knowledge and folklore. The third set of issues relates to geographical indications, especially the extension of the high levels of protection currently available for wines and spirits to other areas.

With regard to the dispute settlement procedure of the WTO, so far there have been 25 complaints relating to the TRIPS Agreement out of 300 WTO dispute settlement panels in total. Of the 25 TRIPS complaints, 10 required panels. It is also worthy of note that in only 7 of the 25 TRIPS complaints were developing countries the respondents and, since the year 2000, only 2 TRIPS disputes have arisen involving developing countries. Thus far, there have been no instances of authorised cross-retaliation for TRIPS dispute settlement panels, however Adrian Otten closed his remarks with the observation that the only WTO cross-retaliation did involve TRIPS in another context, namely the withdrawal of TRIPS obligations by Ecuador following the failure of the EU to bring its banana regime into line with WTO obligations.

Ricardo Melendez Ortiz, Executive Director of ICTSD, Geneva

Ricardo Melendez Ortiz began with the remark that the TRIPS Agreement should be characterised as a standard-setting agreement, the result of imperfect negotiations. He then highlighted the significance of knowledge-based exports in a globalised world and the relationship between intellectual property rights and the impact on policy areas such as education and environmental protection. He commented that intellectual property policy has obtained a global dimension because of TRIPS.

There were four expectations regarding TRIPS. First, there was an expectation that it would put in place the necessary incentives for increased levels of research and development. Second, for developing countries, it was envisaged that TRIPS compliance would assist in attracting higher levels of foreign direct investment (FDI). Third, TRIPS compliance would encourage technology transfer. Fourth, TRIPS would become a proxy for strengthening the rule of law in developing countries.

The UK Commission on Intellectual Property Rights (CIPR) criticised the 'one size fits all' model of intellectual property rights as not delivering developmental benefits to all. Indeed, there have not been significant welfare gains in developing countries as a result of TRIPS. Levels of increase in Patent Cooperation Treaty (PCT) applications, for instance, remain low in developing countries, with the result that most developing countries continue to be technologically backward.

Intellectual property only becomes an important factor in developmental policy *after* scientific and technological progress has been achieved, but the assumption that intellectual property rights are necessary for development is unproven.

In conclusion, Ricardo Melendez Ortiz, said that innovation is needed and must be stimulated. TRIPS and intellectual property do have important roles to play provided care is taken to ensure that they are implemented appropriately.

Mogens Peter Carl, Director General for Trade, European Commission, Former Negotiator of the TRIPS Agreement

Mogens Peter Carl began by stating that the TRIPS Agreement was the result of a shared purpose between a core group of Members of the GATT, representing about 20 developed and developing countries. It was painstakingly drafted and negotiated in open-ended negotiating groups over several years, when the driving forces had been: first, economic self-interest and the protection of private property rights; and, second, defensive interests concerned with the protection of the national policy space, fear of excessive transfers of resources, industrial policy and consumer interests. Few countries were consistently in one camp or the other.

This huge enterprise would have failed if negotiators had not qualified and circumscribed the protection and exercise of private property rights by rules reflecting other aspects of public policy. Intellectual property law, domestic or international, is about the way in which public authorities grant temporary monopoly rights, while carefully defining the limits and circumscribing the exercise thereof.

A typical example is, in relation to patents, the fact that the basic exclusive rights of the patent owner are defined very broadly, granting exclusive rights for 20 years. These exclusive rights are then circumscribed by two pages of detailed rules describing the conditions for the grant of compulsory licences, in itself a balancing act between those who, for consumer or industrial policy reasons, wanted to put maximum pressure on patent owners not to over-exploit their pricing policies, and those who wanted to safeguard against systematic recourse to compulsory licences, which could lead to a hollowing out of patent rights.

It is a question of balance, a balance that was defined reasonably well in the early 1990s. However, times have changed and the balance is an unstable one.

What was adopted in the WTO was a ‘grand compromise’. It created the missing international legal basis for promoting investment in innovation and a powerful tool for encouraging FDI and technology transfer. From the viewpoint of developing countries, TRIPS also set limits on private rights, for example in relation to compulsory licences. The TRIPS negotiations overcame the logjam of the WIPO that had made progress impossible for many years.

However, there were doubts underpinning this ‘grand compromise’. At the time of the TRIPS negotiations, for example, there were concerns that developed countries were pushing for pharmaceutical product patent protection for selfish reasons and the belief that research and development should have incentive structures to encourage private investment in combating diseases prevalent in developing countries. In practice, there has been some limited success in achieving such incentive structures but this is a case of ‘market failure’, that is to say instances where patent protection does not suffice due to a lack of markets in developing countries for medicines. In

these cases, public money is needed for research and development. This has been budgeted for at the EU level, but not yet with a magnitude that corresponds to the needs.

From a very different negative perspective, the TRIPS Agreement has not broken an age-old tradition of illicit copying in several WTO Members, including China, or in prospective Members such as Russia and the Ukraine. In addition, it has failed to help harmonise widely different approaches in key developed countries to some important aspects of the ongoing electronic/software based developments. The evolution of technology has opened up a huge gap between the letter of the law and what is enforceable.

On the positive side, TRIPS has created one of the indispensable bases for globalisation, namely the relative safety of ownership and intangible IP part of international trade and investment. This is difficult, if not impossible, to quantify.

Has the TRIPS Agreement been conducive to development? Again, TRIPS is a necessary but not sufficient ingredient for development, namely because development is driven by a mixture of human development and knowledge, and by investment, partly homegrown, partly imported. Development is also, in large part, the successful by-product of improved governance, of which respect for the rule of law is a key component and of which intellectual property, as defined in the TRIPS Agreement, is an essential element. Again, this is difficult to quantify.

The TRIPS Agreement was, above all, the expression of the highest common denominator of the WTO at the time of its conclusion. We still have to see its positive effects in terms of encouraging expensive research and development in key areas of importance to developing countries. In other respects, solutions have to be found, as had been done in the case of access to essential medicines. But, overall, the balance is correct. The concern is, rather, with the lack of preparedness of the international community to update the TRIPS Agreement whose key elements were negotiated over a decade ago. It is necessary to ask whether the right answers have been found, in particular the right balance between private rights and public policy. Obvious examples are software or design right protection, where the negotiators struggled long and hard and at the end went for the then only possible, simplistic solutions. On implementation, the TRIPS Agreement has hardly put a dent in the ever-growing level of trade in counterfeit goods. On matters of great symbolic and economic importance to developing countries, such as the exploitation of inventions from natural sources and farmers' rights, perhaps even more controversial with the spread of GMOs, the international debate has made little, if any progress. The explosive growth of the internet system, barely imagined a decade ago, is posing other problems in more classical areas such as copyright and trademark protection. On pharmaceuticals, the right hand should act where the left hand alone will not suffice, namely by concerted, public international support on a large scale to encourage research in relation to 'orphan diseases'. It is also a matter of concern that no

agreement has been reached in the WTO on whether to apply the dispute settlement system to ‘non-violation’ cases.

In conclusion, Mogens Peter Carl said that he would like to see a more open and intensive debate about the future of the TRIPS Agreement, but that we have seen from both developing and developed countries that there has been a great wariness on the potential consequences of re-opening a discussion conducted and concluded with great effort a decade ago.

The law has to develop with the times, and preferably on a basis of a conscious decision by the law makers, in this case the representatives of governments meeting in WIPO or the WTO. If there is any area where all agree that new ground should not be broken on substance through dispute settlement interpreting the law, surely it must be the TRIPS Agreement, the quintessential compromise between private interest and public policy.

Finally, Mogens Peter Carl said that what he would like to see launched, perhaps as a result of this conference, would be an informal brainstorming on the future: on what the TRIPS Agreement should look like ten years hence.

Feike Sijbesma, Chairman EuropaBio

Feike Sijbesma said that it was not accurate to speak of the TRIPS Agreement leading to the globalisation of intellectual property rights. Rather, it involved the harmonisation of existing intellectual conventions, setting minimum requirements for developing countries. However, implementation is still a problem.

With regard to the question of whether the TRIPS Agreement has lived up to expectations, on the plus side the WTO dispute settlement procedure has been important, as has the attestation of 'TRIPS compliance' as a new marketing tool for countries. On the minus side, there is still a significant amount of trade in counterfeit goods, delayed implementation in many developing countries, a lack of improved enforcement in middle-income countries, and a need for clarification on what constitutes 'working an invention'.

On the question of whether TRIPS is an obstacle or a booster for development, an effective IPR system is a precondition for effective national innovation in the long term, but 'a nation will never be equal to another by simple imitation. It must be innovative itself' (Hans Christian Orsted, 1829).

There are two perceived problems in the implementation of TRIPS: first, access to health in developing countries; second, the relationship between the Convention on Biodiversity and intellectual property rights relating to life forms and genetic resources.

In terms of access to health, patents are viewed as the villain, but the real problem is that health expenditure in developing countries amounts to $10 per year per capita, while the price per year for an AIDS combination treatment is $2400. Furthermore, no matter how much drug prices decrease, the most important need is a massive investment for the rich parts of the world in combating diseases such as AIDS in developing countries.

In terms of the TRIPS Agreement and the Convention on Biodiversity, the Doha Declaration requires the TRIPS Council to investigate the relationship between TRIPS and the CBD. Controversy surrounds patent protection for microorganisms and genetic material from plants and animals. There are also demands for a requirement in patent laws for the applicant to provide information in respect of the country of origin and proof of having obtained prior informed consent. The CBD had requested that WIPO investigate these issues, while industry wants the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to do this.

In terms of whether solutions to problems encountered with the TRIPS Agreement have been adequate, it must be said that no solutions have yet been implemented. Compulsory licensing will not provide substantial relief for the access to essential medicines. The relationship between TRIPS and the

CBD has not yet been discussed in the TRIPS Council. Industry does not believe in the ‘solutions’ proposed.

The biotech revolution needs a solid IPR system in order to: support the driving role of emerging biotech enterprises in improving the quality of life in a sustainable society; protect ideas in a knowledge based economy; boost economic growth in developed and developing countries; and to attract investment.

In Europe, there is a gap between reality and rhetoric. The Biotech Directive was 10 years in the making but 6 years later is still not implemented in most of the older Member States, including all of the EU’s founding fathers. After half a century of negotiating, meanwhile, there are still no harmonised rules for a Community patent.

Biotechnology holds out the promise of bio-based products for sustainable development, and biotech medicines in the struggle against AIDS and to address unmet medical needs. 50 per cent of drugs currently in the pipeline are for biotech inventions. Biotechnology also holds out great promise for agriculture in developing countries. However, there is not enough investment in new genetic technologies for orphan crops that are critical for food supply and the livelihoods of the world’s poorest people (according to the FAO Report: ‘The State of Food and Agriculture 2003-04’)

In conclusion, Feike Sijbesma said that, to a large extent, TRIPS has lived up to expectations but that there is still a lot of work to be done.

Keith Maskus, Chair of the Economics Department, University of Colorado

Keith Maskus said that he intended to give a trade economists' view of intellectual property rights and said that there were a number of key questions to be addressed. The first question was: are intellectual property rights globalised? The answer was, yes (in relation to TRIPS, the WTO dispute settlement procedure, bilateral agreements and from the perspective of technocrats and the legal sector in most countries) intellectual property rights are globalised. However, when we consider the level of awareness and commitment in the majority of poor countries, intellectual property rights are not globalised.

The second question was: *should* intellectual property rights be globalised? The answer to this question was: yes, because of policy externalities and because intellectual property rights are a pillar of market support, intellectual property rights should be globalised. However, because of socio-economic costs, there are also reasons why they should not be globalised. What is of importance is exploiting flexibilities in the TRIPS Agreement, which leave considerable room for argument about how well or how equitably intellectual property rights are globalised.

The third question was: has the TRIPS Agreement met expectations? The answer to this question depends on whose expectations are being considered. In this regard, there is considerable dissatisfaction among developing country governments, for a number of reasons: first, due to the weak link to market access; second, due to the limited success in achieving technology transfer; third, due to the need for broader reforms; and, fourth, due to concerns about the impacts of the TRIPS Agreement in agriculture, medicine, science and education.

The fourth question was: is the TRIPS Agreement a boost for development? A positive case can be made on grounds that intellectual property rights support market deepening and product quality, even at low development levels; support greater flows of international technology transfer flows; offer scope for improving commercialisation of publicly supported research; and can improve scope for implementing critical new technologies.

However, there remain a number of obstacles to development as a result of the TRIPS Agreement, notably: heavy demands on development budgets and expertise; the limits of policy space for learning and imitation; and the fact that stronger protection could reduce technology flows to the poorest countries. A neutral case can also be made, namely that the impact of the TRIPS Agreement may be slight in poor countries.

A number of implementation problems remain in developing countries. Some of these relate to relations between government ministries within developing countries, while others relate to notifications to the TRIPS Council under Article 66.2 of the TRIPS Agreement. There is also the question of whether

there is technology transfer into developing countries. The answer is that we do not know whether this is occurring or not.

In his concluding remarks, Keith Maskus said that the TRIPS Agreement had been a qualified success, that it needs to be implemented in good faith. He also said that it should be reiterated that there is a need for careful consideration of the appropriate standards and flexibilities for developing country WTO Members.

Federico Alberto Cuello Camilo, Research Professor of Economics at Pontifical University Madre Y Maestra, Santo Domingo, Dominican Republic, former Ambassador of the Dominican Republic to the WTO

Federico Alberto Cuello Camilo said that there were high costs if an intellectual property system goes wrong in developing countries, as the UK Commission on Intellectual Property (CIPR) has made clear, due to other anti-competitive measures in developed countries. Bilateral pressures exist which often prevent the use of TRIPS flexibilities in developing countries, although such cases do not reach the WTO dispute settlement procedure since they are said to have been 'adequately' handled bilaterally. These bilateral pressures include the removal of diplomats from their national trade delegations to Geneva and biased capacity building efforts on behalf of developed countries.

Bilateral pressures are also contained in the draft Central American Free Trade Agreement (CAFTA). With regard to Article 39.3 of the TRIPS Agreement (protection of undisclosed information), for instance, the CAFTA contains, in Article 15.10, periods of data exclusivity of at least 5 years for pharmaceutical products and at least 10 years for agricultural chemical products, even though these periods of data exclusivity are not prescribed in the TRIPS Agreement itself. In relation to non-violation disputes, the draft CAFTA also contains, in Annex 20.2 paragraph 1(c), provisions that allow for dispute settlement proceedings wherever a party considers that an actual or proposed measure of another party causes or would cause nullification or impairment. These proposed CAFTA provisions would limit the ability of CAFTA member countries to utilise flexibilities available in the TRIPS Agreement.

In his concluding remarks, Federico Alberto Cuello Camilo said that a pro-competitive approach to the protection of intellectual property rights should be promoted both nationally and internationally.

Wolfgang Starein, Director of Enforcement and Special Projects Division, World Intellectual Property Organisation

Wolfgang Starein said that there had not yet been sufficient time to demonstrate the economic benefits of the TRIPS Agreement.

The debate has been distracted by the access to essential medicines debate, but that the TRIPS Agreement is primarily an issue for developing countries because of WTO membership. WIPO provides assistance in intellectual property laws and regulations for developing country governments. Wolfgang Starein said that he himself commented personally on the draft intellectual property legislation of developing countries.

In his concluding remarks, Wolfgang Starein said that there remained shortcomings in the field of enforcement and that additional training is required for national customs officials and the judiciary.

QUESTIONS TO THE PANELLISTS FROM PANEL 1

Since every country that became great economically did so by copying, to what extent is the true aim of the TRIPS Agreement to prevent that process of achieving economic progress by copying ever happening again?

In response, Mogens Peter Carl said that it is not possible to base economic development simply on what others are doing. Instead, what is needed is the right balance between private rights and technology transfer.

Keith Maskus said that the issue is one of dealing with a monopoly on innovation.

A report commissioned by the Commonwealth Secretariat, entitled 'An Agenda for the Development Round of Trade Negotiations in the Aftermath of Cancun' and written by Nobel Laureate Joseph E. Stiglitz (Columbia University) & Andrew Charlton (Oxford University) was published on 21 July 2004. Could the Panel comment on the report's suggestion that the TRIPS Agreement should be rolled back and switched to different forum, referring in particular to the situation in least-developed countries and the impact of the TRIPS Agreement?

In response, Federico Alberto Cuello Camillo asked: 'where do we move to and what are the alternatives?' He said that the WTO has been reasonably effective. Ricardo Melendez Ortiz said that he did not doubt the value of intellectual property rights, but that the 'one size fits all' approach does not work. He said that what is needed is to ensure international technology transfer.

Keith Maskus said that few least-developed countries were in a position to be domestically innovative; there are therefore good reasons to exclude least-developed countries from TRIPS obligations for many years to come.

Adrian Otten pointed out that the 2006 deadline for introducing patents for pharmaceutical products in least-developed countries had already been extended to 2016 by the 30 August 2003 WTO Decision on the Doha Declaration, the TRIPS Agreement and Public Health. He then explained the general and specific flexibilities in relation to compulsory licensing that are set out in the 30 August 2003 Decision.

Mogens Peter Carl said that 'one size fits all' is a misrepresentation and that the TRIPS Agreement is akin to an EU Directive in terms of the flexibilities it contains for WTO Members. He also said that the role of reverse engineering in Japanese and German economic development was not contrary to intellectual property rights.

Could the panellists comment on the relationship between plant variety rights and the UPOV Convention?

In response, Mogens Peter Carl said that Article 27(3)(b) of the TRIPS Agreement does not go very far in relation to the UPOV Convention and that the EU was attempting to get the Doha Round of multilateral trade negotiations to include a substantive review of this provision of the TRIPS Agreement. He said that TRIPS is a balance between rights and obligations and that if countries are going to make concessions, this will be in the multilateral context, except for geographical indications, for example, in relation to geographical indications for wines and spirits originating from Chile.

Is not the reliance on markets for research and development into orphan drugs over-reliant on intellectual property rights?

In response, Mogens Peter Carl said that he agreed and that there needs to be a greater focus on public-private partnerships for new research efforts in relation to orphan drugs.

Ricardo Melendez Ortiz said that the biggest challenge was how to encourage innovation. He referred to Jerome Reichman's pro-competitive approach and said that this would require, for example, access to test data submitted for the purposes of regulatory approval procedures (Article 39.3 TRIPS). He also said that there was a need for open source access to research and development into new drugs.

In relation to the TRIPS Agreement, the Doha Declaration and the HIV/AIDS pandemic, what is needed is technical assistance for developing and least-developed countries on how to use compulsory licenses. Why did the list of least-developed countries set out on the 30 August 2003 Decision not include providers of generic drugs and the countries that need them? Also, what role will bilateral agreements play in the application of the 30 August 2003 Decision?

In response, Adrian Otten said that the 30 August 2003 Decision must work and that developing countries should be given technical assistance to make sure that it does work. He said that the WTO had organised 7 regional workshops with the World Health Organisation (WHO) on the implementation of the 30 August Decision and that these workshops had also involved civil society groups. He reported that developed countries were amending their national legislation in order to be able to meet demand as exporters of generic medicines under the 30 August procedures.

Mogens Peter Carl said that no developing countries have so far come forward to take advantage of the 30 August mechanism, despite the efforts of the pharmaceutical industry to encourage this. He also pointed out most medicines are not patented and that few of the medicines that are patented appear on the WHO essential medicines list. He said that the 30 August Decision is the tip of the iceberg as regards to ensuring access to essential medicines in developing countries.

Keith Maskus said that taxpayers in rich countries should to step forward to provide incentives for research and development into essential medicines.

Feike Sijbesma said that fairness of welfare distribution is difficult to achieve through the TRIPS Agreement alone.

In relation to biodiversity, particularly the interface between the TRIPS Agreement and the Convention on Biodiversity, what should be done?

In response, Adrian Otten said that the TRIPS Council was addressing the relationship between TRIPS and the CBD and that the issue was on their agenda.

Drawing Panel 1 to a close, in his concluding remarks Lars Anell said that the effects of the TRIPS Agreement were far beyond what TRIPS negotiators had anticipated and that some issues raised today seemed almost completely unrelated to the existence of TRIPS. He pointed out that 50-60 countries had actively participated in the TRIPS negotiations and said that acceptance of the TRIPS Agreement was a Uruguay Round trade-off. He concluded that, for developing countries, the TRIPS Agreement was preferred to bilateral pressure and protectionism and that, in this context, TRIPS-plus bilateral agreements seemed unfair.

PANEL 2: ENFORCEMENT CHALLENGES

Moderator: István Major, Deputy State Secretary, Hungary, former Ambassador of Hungary to the WTO and former Chairman of the TRIPS Council

Paul Vandoren, Head of Unit, Trade DG, European Commission

Paul Vandoren said that he would like to tackle the last question outlined by the moderator: is it time for a new strategy for enforcement? He said that he would answer this question in the context of the European Commission's *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, published on 23 June 2004.

The protection of intellectual property rights is always at the fore of European Commission concerns because, from the point of view of the protection of right-holders, intellectual property rights provide incentives and rewards for creativity and innovation, together incentives for investment, job creation and the protection of tradition. The absence of intellectual property rights enforcement, on the other hand, is a problem for public health, with dangers arising due to the counterfeit food products, pharmaceuticals, toys, seeds, electrical appliances, automobile and aircraft spare parts.

Enforcement of intellectual property rights is also important due to the issue of public order and security, with piracy and counterfeiting having links with organised crime and terrorism.

There are a number of legal commitments that countries must meet:

- at a national level, an obligation to enforce national legislation;
- at a bilateral level, there are the Europe Agreements, which provide the framework for bilateral relations between the European Communities and their Member States on the one hand and the partner countries on the other, and European-Mediterranean Cooperation Partnership for South-Mediterranean and Middle East Countries (MEDA);
- at a multilateral level, the WTO Agreements, including TRIPS, and the WIPO conventions.

The European Commission has split competences with respect to intellectual property policy: relations with third countries are dealt with by DG Trade, policy at Community level is dealt with by DG Internal Market, external border matters are dealt with by DG Taxation and the Customs Union (TAXUD), technical assistance is dealt with by DG AIDCO (EuropeAid Cooperation Office), DG for External Relations (RELEX) and the EU's national delegations in third countries, while organised crime is tackled by DG Justice and Home Affairs and the European Anti-Fraud Office (OLAF).

At Community level, actions include the Enforcement Directive, which harmonises enforcement legislation inside the EU, and the revised Customs

Regulation, which sets up a regime to seize counterfeit and pirated goods at the EU border. There is also a strategy for enforcement in third countries, which reacts against the violation of intellectual property rights outside the EU.

Developed and developing WTO Members are, since 2000, legally bound to respect minimum standards of intellectual property protection, but there has been an increase in piracy and counterfeiting in spite of efforts to introduce global minimum standards of IP protection. The link between systematic violations of intellectual property rights and organised crime is increasingly visible, with a substantial share of pirated goods originating from outside the European Community.

There are continuing problems of enforcement in third countries that require political will to be overcome. The link between enforcement of intellectual property rights and development is a difficult message to pass on, but there have been sincere efforts by certain countries to address the problem. The European Community can help by assisting developing countries in drafting intellectual property legislation, as it has already done, and what is now required is technical assistance to produce effective enforcement.

A website setting out the complete results of the European Commission's *Survey on Enforcement of Intellectual Property Rights in Third Countries* is available at:

http://europa.eu.int/comm/trade/issues/sectoral/intell_property/survey_en.htm

The recommendations made in Part II of the European Commission's *Strategy for the Enforcement of Intellectual Property Rights in Third Countries* seek to address the problem. These proposed actions fall under the following headings:

1. The need to identify problem countries through the periodic assessment of the situation in third countries via questionnaires, statistics and information collected by EU Delegations;
2. The use of multilateral and bilateral agreements as mechanisms to achieve better IP enforcement;
3. The use of political dialogue, intensifying co-operation with other countries particularly through the role of EU Delegations, to make clear to the EU's trading partners the importance of IPR enforcement;
4. The use of incentives, such as technical cooperation through training programmes, seminars, assistance with the preparation of laws and capacity building;
5. The use of sanction mechanisms such as the dispute settlement procedure of the WTO, bilateral agreements and the Trade Barriers Regulation;
6. The creation of public private partnerships, achieving closer co-operation with right-holders and associations;
7. Raising awareness by drawing on the EU's own experience to inform the public about the negative impact of IPR violations and inform right-holders of how to address IPR violations;

8. Improving institutional cooperation within the EU, clarifying roles for the public and identifying contact points.

In his concluding remarks, Paul Vandoren said that the time has come for the TRIPS Council to hold a debate on enforcement issues. So far, there has been no WTO dispute settlement panel on TRIPS enforcement (and few Trade Barriers Regulation cases at European Community level). He said that what is required is political dialogue, awareness raising and greater recourse to public-private partnerships.

Elisabeth Ponsolle des Portes, CEO of Comité Colbert, France

Elisabeth Ponsolle des Portes explained that Comité Colbert is a non-profit association of 65 French brands in the luxury sector, created in 1954 and representing sectors including: porcelain; crystal; silverware; leather; fashion; champagne, wines and cognac; jewellery; and services.

Comité Colbert is playing a key role in the filed of IP, tackling the problem through providing an input into legislative activity including: at a national level, the Longuet Law of 1994 and the Perben Law of 2003; and, at the European level, the Directive on Counterfeiting and Piracy and the Customs Regulation. A key contribution of Comité Colbert in this respect has been to highlight the link between counterfeiting and organised crime. Comité Colbert also plays an important role on enforcement issues through permanent contacts with the relevant authorities in France and abroad and, in relation to enforcement, through media campaigns in France and abroad, several examples of which Elisabeth Ponsolle des Portes gave in her presentation.

The current state of play in relation to the counterfeiting of luxury products is that all countries are distributors of counterfeit goods and all brands are the victims of counterfeiting. 90 per cent of counterfeit goods in the luxury sector originate from China, this constituting a parallel economy that is threatening companies that are respecting WTO rules. Within the EU, continuing counterfeiting problems, particularly in Italy, are undermining attempts to negotiate for higher standards in third countries.

Creating brands is not a luxury for the so-called developing countries. Companies in Morocco, for example, are finding that their products are being copied by Chinese and Dutch counterfeiters and there is a need to protect goods originating in developing countries in order to prevent counterfeiting of locally produced goods.

In this regard, the enforcement mechanisms of the TRIPS Agreement provide a good framework, but the TRIPS Council is not evaluating the quality of the technical assistance and enforcement programmes offered to developing countries. Many technical assistance programmes are implemented through the World Intellectual Property Organisation (and notably the Advisory Council on Enforcement), the Technical Assistance and Information Exchange Unit (TAIEX) of DG Enlargement, the World Customs Organisation, and on a bilateral basis. However, there is a need to evaluate the impact of technical assistance given, for example, to customs officials and the judiciary in developing countries on an annual basis. In France there is currently no specific training on intellectual property in the academic courses taken by judges and there are no specialised IP courts.

The ideal strategic plan of action would involve: first, the training of judges and the setting up of specialised courts; second, the training of customs officers; third, the training of police officers; and, fourth and most importantly, the evaluation of technical assistance programmes.

Elisabeth Ponsolle des Portes concluded by identifying two weaknesses in the enforcement provisions of the TRIPS Agreement, namely: Article 57 (right of inspection and information) which, she said, contains vague wording which states that ‘Where a positive determination has been made on the merits of a case…’, this being a vague wording which has led to the non-disclosure of information by customs authorities in many countries; and Article 60 (*de minimis* imports) which states that ‘Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers’ personal luggage or sent in small consignments’. This *de minimis* provision is objected to as a matter of principle by the Comité Colbert.

Elisabeth Ponsolle des Portes ended by saying that counterfeiting is supported by organised crime and, as such, is an issue to be addressed at the highest international level.

Betty Mould-Iddrisu, Director of the Legal and Constitutional Affairs Division, Commonwealth Secretariat, London

Betty Mould-Iddrisu said that Article 1 of TRIPS stipulates that the Agreement only sets minimum standards and that WTO Members are not required to implement more extensive protection than is required by the TRIPS Agreement. In reality, however, implementation of the TRIPS Agreement has entailed significant extensions in the scope and administration of intellectual property rights for developing countries, several of which have not hitherto provided protection of intellectual property rights.

For developing countries, at least those in Sub-Saharan Africa, interpretation, implementation and enforcement of the TRIPS Agreement has required resources and capacity in excess of those existing in their countries. In this respect one must commend the WIPO and, recently, the Commonwealth Secretariat for their assistance to WTO Members in enhancing their capacity to meet these obligations.

The obligation on developing country WTO Members to enact domestic legislation to implement the TRIPS Agreement by January 2001 had proved to be problematic for some countries. Problems had been encountered in Ghana and Kenya. The apparent non-implementation of TRIPS by some developing countries should be viewed against the backdrop of these local problems.

The 2002 Report of the UK Commission on Intellectual Property Rights states that intellectual property systems may introduce distortions detrimental to the interests of developing countries. These findings are reiterated in the recent Commonwealth Secretariat report, entitled 'An Agenda for the Development Round of Trade Negotiations in the Aftermath of Cancun'. However, Article 8 of the TRIPS Agreement does suggest flexibility in national legislation to ensure socio-economic development in important sectors, although this leaves WTO Members with the difficult task of balancing their socio-economic interests with compliance with other provisions of the TRIPS Agreement.

There is a 4- or 5-year differential between implementation and enforcement of the TRIPS Agreement in Sub-Saharan Africa. The transformation in existing legal, economic and political structures is crucial for effective enforcement and this transformation is best achieved if the countries concerned are able to appreciate the relevance of intellectual property to their national development.

Countries in Sub-Saharan Africa have themselves struggled to understand the implications of the TRIPS Agreement on their national development in terms of economic costs, legislative infrastructure and administrative framework. The costs of bringing national legislation into conformity with the TRIPS Agreement and strengthening the domestic institutions that will be charged with implementing the new laws are costs that are not incurred by developed countries.

TRIPS was formulated in the belief that an internationally harmonised system of intellectual property protection enhances trade and reduces distortions and impediments to international trade, but even the most optimistic proponents of TRIPS cannot honestly assert that this is close to fruition in Sub-Saharan Africa. Instead, the stark reality is that statistics show that, globally, only 0.2 per cent of patents were registered in developing countries while 99.8 per cent have been registered in developed countries. In Africa, the statistics are even more alarming, with an estimated 0.02 per cent of patents registered globally originated in Africa. Consequently, there is deep-rooted scepticism by governments in many African countries that additional technology transfer on reasonable terms will be forthcoming.

Betty Mould-Iddrisu stressed the need for a stronger basis for cooperation to overcome concerns that the expected benefits of TRIPS are not occurring. This cooperation could be provided through Articles 66 and 67 of TRIPS, which commit developed countries to use best efforts to identify measures they could take to encourage technology transfer and to build a sound and viable technological base in the recipient countries.

On the question of piracy and counterfeiting, too much protection could be as damaging as too little and is also capable of causing distortions to trade and hindrance to the legitimate aspirations of the consuming countries. Africans should try to formulate specific African responses to issues of enforcement, since they are the ones with first-hand experience and knowledge of the benefits that specific enforcement of intellectual property rights can bring to a country's domestic economy.

In her concluding remarks, Betty Mould-Iddrisu said that it is apparent that the benefits of the TRIPS Agreement have been lop-sided in favour of a few developed countries and that nowhere is this manifested more clearly than in the failed Cancun Round and the WTO's handling of the access to medicines debate. She ended with four statements:

1. African countries were committed to enforcement of intellectual property rights;
2. The TRIPS Agreement requires substantial revision;
3. There is a need to ask whether the WTO is the appropriate institution to administer international intellectual property agreements;
4. The low level of expenditure on technical assistance for developing countries must be redressed.

Takashi Kugai, Councillor, IPR Headquarters, Cabinet Secretariat, Japan

Takashi Kugai outlined the strengthening of measures to combat counterfeiting and piracy in Japan. He began by setting out the chronology of Japan's intellectual property strategy, which began in February 2002 with a policy statement by Prime Minister Koizumi, who spoke of Japan as an 'IP-based nation'. This was followed in March 2002 by the establishment of a Strategic Council on Intellectual Property within Japan's Government. In July 2002, an Intellectual Property Policy Outline was published. This was followed, in November 2002, by the Basic Law on Intellectual Property. In March 2003 the Intellectual Property Strategy Headquarters was established and, in July 2003, the Intellectual Property Strategic Program was adopted. Finally, in May 2004, the revised Intellectual Property Strategic Program was published.

Takashi Kugai then outlined the characteristics of an IP-based nation which, he said, was founded on a knowledge-based economy. At a macro level an IP-based nation was characterised by productivity, which is critical to economic growth. At a micro level, an IP-based nation is characterised by intangible assets and a shift from static to dynamic competition. Above all, what is required is a need to foster 'sustainable' innovation.

An increasing number of Japanese companies are suffering from counterfeiting overseas, with 90 per cent of counterfeit and pirated goods manufactured and distributed in Asia. The types of counterfeit goods have expanded from trademarked to industrial design-protected and patented goods. There is a link between advances in technology and large-scale distribution of counterfeit and pirated goods, and he gave examples of infringements overseas, including:

- Electronics, where counterfeiters had established homepages to sell counterfeit liquid crystal televisions and DVD players by mail order;
- Motorbikes and cars, where infringement of trademark and design rights is common;
- Toys and daily necessities, where underground markets exist in which counterfeit goods are distributed in large quantities;
- Videos and DVDs, where numerous pirated versions of movies are distributed in advance of the public presentation of a new work.

There has been a rapid increase in the number of stops at the border by Japanese customs officials detecting counterfeiting and piracy, with trademark infringement particularly commonplace. The number of arrests for infringement of intellectual property rights has also increased significantly in the last five years.

An action plan of measures to be taken against counterfeiting and piracy in Japan's overseas markets includes:

- Using bilateral and multilateral forum building consensus to strengthen IP law enforcement;

- Advocating a treaty and ministerial declaration for preventing proliferation of counterfeit and pirated goods;
- Support for developing countries to increase their capacity in IP law enforcement;
- The introduction of an investigation system on IP infringement in overseas markets upon right holders' claims;
- Enhancing the function of Japanese embassies and Japan External Trade Organisation (JETRO) offices for IP protection.

Measures are also being taken at the international level, including the G8 Action Plan (item 16), agreed at the Sea Island Summit in June 2004, which undertook to support developing countries' ability to attract knowledge-based investment and promote innovation by working with them to curb piracy and counterfeiting, which increasingly damage domestic as well as international business. At a bilateral level, the EU-Japan agreement in Tokyo in June 2004 contains a commitment to set up a Joint Initiative for IPR Enforcement in Asia.

With respect to additional measures to be taken against counterfeiting and piracy at national borders, there is a need:

- To tighten border control and reinforce customs functions. He reported that the Japanese Customs Law was amended in April 2004, which enables customs to disclose information on alleged infringers to right holders so that right holders can bring infringement claims to court;
- To examine further measures, such as the regulation of cargos for which the determination of infringement is difficult, and the regulation of private imports.

In terms of Japanese domestic regulations, there is a need to consider a wide range of regulatory strategies, taking into account the seriousness of high levels of trade in counterfeit and pirated copies via the internet, and a need to consider strengthening measures to prevent the overseas leakage of trade secrets, such as know-how. In March 2003, the Ministry of Economy, Trade and Industry (METI) published guidelines for corporate management of trade secrets and the prevention of leakage of technology.

In his concluding remarks, Takashi Kugai reported on the establishment of an Intellectual Property High Court in Japan. He said that the Bill had passed the Diet in June 2004 and that the establishment of the IP High Court was envisaged in April 2005.

Zhao Hong, Deputy Director General, Ministry of Commerce, China

Zhao Hong began saying that the TRIPS Agreement was characterised by complexity both in the ideas and theory underpinning it and the legal text itself. In terms of enforcement challenges, she identified the particular strengths of the TRIPS Agreement as being: first, its specific enforcement provisions (Articles 41-61); second, the national treatment (Article 3) and most-favoured-nation (Article 4) provisions; and, third, the recourse to the dispute settlement body of the WTO. She said that the weakness of the TRIPS Agreement was that it only established minimum standards rather than harmonisation. As a result, TRIPS enforcement depends on the implementation of national law.

Zhao Hong then turned to the question of how to tackle piracy and counterfeiting and said that three factors were crucial: first, enhancing public awareness; second, national enforcement policy; and, third, commercial or corporate strategy, particularly with regard to the reasonable pricing of products for local markets and reforms in product market modalities.

With regard to the cost of non-implementation of TRIPS vs. the cost of implementation of TRIPS, there is no actual economic analysis but, on the face of it, non-implementation by WTO Members creates a bad reputation and may lead to the risk of losing cases in the WTO dispute settlement procedure. The cost of implementation, on the other hand, includes: legislative costs; administrative costs; judicial costs; public education costs; and training costs for enforcement officers.

Zhao Hong then asked: is enforcement of intellectual property rights a real priority for developing countries? She said that in answering this question it is necessary to consider both the effectiveness of capacity building programmes and the implications of intellectual property rights enforcement for public health. Policy priorities that need to be addressed by most developing countries include:

- reduction of poverty;
- resolving public health problems;
- achieving political stability;
- economic reforms;
- combating drug trafficking and smuggling;
- combating corruption;
- improving environmental standards;
- improving literacy rates;
- capacity building in infrastructure and human resources;
- establishing a legal framework to achieve the rule of law.

Zhao Hong then outlined China's priorities and policies in relation to intellectual property rights and said that IPRs played an important role in:

- Establishing a bona fide market order and achieving fair competition among all market players;
- Promoting science and technology innovation and thus providing an impetus for sustainable economic development;
- Creating an environment conducive to attracting more high quality investment and commercial activities into China;
- Transforming China's export products from labour-intensive low-end products to technology-intensive, environmentally friendly, high-end products.

China's initiatives in relation to the enforcement of intellectual property rights include legislative, judicial and administrative reforms. Challenges still lie ahead, with piracy remaining a difficult situation with a population of over 1.3 billion people, including 1 billion peasants, in China today.

In conclusion, Zhao Hong said that China's new strategies for improving enforcement of intellectual property rights include:

- More dialogue with and more input from developed countries, for example through technical cooperation initiatives;
- An acknowledgement of the need to solve the unbalanced interests in intellectual property between developed and developing countries, for example in relation to traditional knowledge and bio-resources in which developing countries have certain advantages;
- Acknowledging the role of patents as impediments to small- and medium-sized enterprises, which can be addressed by adopting stricter national rules on the granting of patents;
- Addressing measures to avoid abuse and misuse of exclusive rights by intellectual property holders.

QUESTIONS TO THE PANELLISTS FROM PANEL 2

Could the Panel comment on the status of intellectual property rights as private rights under the TRIPS Agreement?

In response, Betty Mould-Iddrisu said that Africa has struggled with holding intellectual property rights as private rights when the bulk of inventors are unable to enforce their rights. Therefore, she said, what is needed is a greater role for the state.

Paul Vandoren said that the Statement of the Chairman of the General Council of the WTO on the 30 August 2003 Decision on access to medicines cannot take anything away from the Decision itself and that the European Community's belief is that the legal value of the Chairman's Statement should not be upgraded to undermine the Decision.

In most African countries, there is procedural but not substantive examination of patent applications. What remedies can be sought?

In response, Betty Mould-Iddrissu said that she recognised the problem being described and said that attempts have been made to improve the situation in Africa through the African Regional Intellectual Property Organisation (ARIPO), namely by bringing national patent offices in Africa within a regional intellectual property organisation, in doing so maximising efforts. She said that ARIPO has been undertaking substantive examinations for the past decade.

Could the Panel comment on the statement that more is due from the TRIPS Agreement in terms of brands than for patents, breeders' rights, etc.?

In response, Elisabeth Ponsolle des Portes said that creating brands is creating wealth for countries. For example, she said, recent experience in China and Korea was that locally produced global brands, such as Samsung in Korea, had demonstrated the importance of brands. She also said that geographical indications have great potential for developing countries and that Comité Colbert is prepared to help developing countries in achieving products with added value.

Paul Vandoren said that communicating the benefits of intellectual property is a difficult and important task.

A speaker from the floor said that: *It is difficult for a least-developed country, such as Lesotho, to see what the role of the state would be. States should be concerned with the policy goal of development. Intellectual property protection should follow. Furthermore, traditional knowledge is seen as being in the public domain.*

In response, Betty Mould-Iddrisu said that intellectual property enforcement is a fundamental duty of government. She said that she would not disagree that intellectual property rights are for the rich, but that local musicians, designers,

etc. are in the poorer category of society and also need protection through intellectual property rights.

What other types of products are the Panel thinking about in relation to geographical indications, other than wines and spirits?

In response, Zhao Hong said that geographical indications are a potential marketing tool for developing countries, but that she recognises that geographical indications can relate to collective rights as well as private rights and that it is unclear what system of geographical indications is best.

PANEL 3: IPRS, HUMAN RIGHTS AND THE PUBLIC DOMAIN

Moderator, Istvàn Major, Deputy State Secretary, former Ambassador of Hungary to the WTO and former Chairman of the TRIPS Council

Geertrui van Overwalle, Professor of Law, KU Leuven

Geertrui van Overwalle said that human rights is a two-fold concept: first, it relates to positive rights for intellectual property right holders (as embodied in Article 27(2) Universal Declaration of Human Rights) and for third parties (Article 5 UDHR); second, it has a negative side in that the rights of others can be a limitation for intellectual property right holders, and because IP rights can limit the rights of third parties, for example in relation to the debate on access to essential medicines.

The term 'public interest' is an abstract concept, involving both negative and positive aspects. A concrete definition would involve a number of elements, including: *ordre public*; morality; consumer protection; the protection of life of animals and plants; and public health as part of the notion of public interest rather than through the language of human rights.

In relation to intellectual property rights and the public interest, account needs to be taken of the public interest in seeing economic progress and technological development for society on the one hand, and needs to take account of public health on the other hand, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health and the subsequent 30 August 2003 Decision of the WTO.

The relationship between intellectual property rights and the public domain can be described as 'the tragedy of the commons', a metaphor for people overusing shared resources (see Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, Vol. 280, Issue 5364, 698-701, 1 May 1998).

Furthermore, the existence of patent thickets (see Carl Shapiro, 'Navigating the Patent Thicket: Cross-Licenses, Patent Tools, and Standard Setting', in *Innovation Policy and the Economy Volume 1*, Adam Jaffe, Joshua Lerner and Scott Stem (eds.), MIT Press, 2001) means that upstream royalty stacking is a bar to downstream innovation.

However, Dan L. Burk and Mark A. Lemely, in their paper 'Policy Levers in Patent Law' (*University of California at Berkeley Law School Public Law and Legal Theory Research Paper Series* Research Paper No. 13, 2003), set out mechanisms to clear the patent thicket including the use of cross-licences and patent pools.

Geertrui van Overwalle concluded by saying that compulsory licenses also have a role to play as a means to break through the fence and allow access to the presently enclosed resources.

Vandana Shiva, Founder of the Research Foundation for Science, Technology and Ecology

Vandana Shiva said that the TRIPS Agreement does not globalise intellectual property: it redefines it. This is epitomised by Article 27(3)(b) of the TRIPS Agreement. The TRIPS Agreement has huge implications for human rights and the patenting of life affects humans because we *are* biodiversity.

80 per cent of the world's population make a living through farming. The cost of seeds is a burden. The first suicide due to the cost of seeds in India had now been recorded. The Indian Patent Law of 1970 had deliberately included exemptions for farmers' rights and pharmaceutical product patents.

The patenting controversies surrounding Neem, Ricetec and the Basmati patent are all symptomatic of patent rights as a system of "globalised ignorance".

The African Group submission before the Cancun WTO Ministerial Meeting stressed the adverse impact of the TRIPS Agreement for developing countries.

In conclusion, Vandana Shiva said that revisiting TRIPS on the basis of a mandatory review is an obligation on the international community.

Lawrence Lessig, Law Professor at Stanford University, Open Software activist

Lawrence Lessig said that he wanted to start with a reframing of the Panel's questions as having the answer: 'obviously'.

There is a tradition of promoting science and the useful arts in the United States. Intellectual property rights today are crafted for the specific purpose of the development of culture and knowledge, but not all culture and knowledge is commercial. For example, libraries, archives and university knowledge are not commercial.

The intellectual property regime creates a burden when reckoned with the potential of the digital environment.

The Brewster Kahle archiv.org tracks down copyright owners of out of print books. It fulfils an important function because copyright presently hinders access to out-of-print works in ways that have nothing to do with incentives that copyright seeks to create. The war on piracy is making transformative culture illegal.

The Office of the United States Trade Representative (USTR) policy of rejecting the balance of TRIPS through TRIPS-plus bilateral trade agreements is profoundly unjust when balance was the ideal.

Lawrence Lessig asked: why has it taken us so long to recognise that there is an imbalance between intellectual property rights and other imperatives? It is rent-seeking extremism that has created extremism on the other side, with people openly questioning whether intellectual property rights promote innovation. This is a failure of democracy – a failure to escape the rent-seeking model.

In conclusion, Lawrence Lessig said that those who believe in intellectual property have an obligation to ensure that it serves its intended objectives.

Tim Hubbard, Geneticist, Sanger Institute, Cambridge (UK)

Tim Hubbard said that the consequences of paying retrospectively for research and development via sales were that: first, patent 'thickets' had emerged that were inhibiting research and development; second, paying retrospectively leads to a lack of competition and high prices, with only 10 per cent of profits from drug sales spent on research and development for new products; third, it encourages the market to reward research and development that optimises profitability rather than therapeutic benefit; and, fourth, it excludes those who cannot pay high prices, both in developed and developing countries.

The justification of the TRIPS Agreement is to prevent 'free riding'. However, are there other ways of avoiding free riding? By adopting TRIPS, the expectation is that there will no longer be free riding on the research and development of others but, since the equivalent of 0.1 per cent of GDP is invested in new drug research and development, since sales of drugs are approximately 1 per cent of GDP in most countries, and since 10 per cent of the sales price of drugs supports research and development, countries that maintained this research and development contribution *by any other means* would also not be free riding.

In this regard, the Global Treaty Proposal put forward by Tim Hubbard and James Love (see PloS Biology, 17th February 2004, www.plos.org, public library of science) advocates a national research and development obligation, whereby each country commits a minimum percentage of GDP on health care related to research and development (set by the World Health Organisation), leading to increased development of public goods. Countries meeting research and development obligations would be free of TRIPS and could choose their own policies, including: buying generic medicines; targeting their own health care issues; and building research capacity.

Whereas current funding structures favour payments by the public in the form of taxation and health insurance, for post-R&D drug production and marketing, the Global Treaty Proposal would instead promote payments by the public for academic R&D, commercial R&D (through a national R&D obligation), as well as for the purchase of generic drugs.

Furthermore, the Global Treaty Proposal allows competition between prizes for innovation, grants (such as those awarded by the National Institute of Health in the USA) and open source research results. Open source has already played a significant role in the success of the Human Genome Project and it is proposed to extend this model of open source to medical research, as the Economist magazine has recently predicted in two articles on 10th June 2004 (*Beyond Capitalism? The open-source model can be applied to goods other than software, but it has its limits*, and *An Open-Source Shot in the Arm?*). In addition, the G8 announced on 11th June 2004 that it would support directly funded collaborative research models in the form of a global HIV vaccine plan styled on the Human Genome Project approach.

The secret of open projects lies in, first, the existence of legal structures to guarantee future success and, second, the existence of mechanisms for sustainable collective management. Knowledge is of greatest benefit when it is freely accessible to all, while basing economic competition between nations on regulated access to knowledge is bad for all of us. Certainly, the creation of knowledge has to be paid for, but there are alternatives to intellectual property that have been shown to work.

WIPO has a role to play in advocating an open approach to intellectual property, with its own vision of itself (according to its web site statement) being the 'maintenance and further development of the respect for intellectual property throughout the world'. Furthermore, when WIPO became a specialist agency of the UN in 1974, the founding agreement between UN states established the mandate of WIPO as being 'to stimulate "creative intellectual activity"'. As reported in Nature magazine (424, 10th July 2003), a group of leading scientists and economists wrote to WIPO drawing attention to the explosion of open and collaborative projects to create public goods (including the Human Genome Project) and asking WIPO to promote a more 'open' model of innovation that does not rely on patents.

But does the existing patent system reveal knowledge? In the past, when there were relatively few scientists, patents provided an incentive to reveal information. However, today, there are a far greater number of scientists who go to the same meetings, read the same research papers and think that they have the same ideas at the same time. Under these conditions, the first to reveal should get the credit, so that there is no need for patents. Rather, originality should be characterised as undetected plagiarism.

Moreover, patents, copyrights and trademarks can be characterised as knowledge resources legislation. In the case of health care, this amounts to 'warrants to monopolise drugs', or WMD, which is more commonly an acronym for Weapons of Mass Destruction. This is an appropriate comparison since patents that block access to essential medicines are weapons of mass destruction. Given that Libya has recently renounced WMD, isn't it time that we talked about giving up the other type of WMD, the type that actually kills people by depriving them of access to medicines?

The benefit of not paying for R&D via sales is that it removes the need for monopolies in the form of patents by removing restrictions on other research and allowing competition in drug production, reducing prices and allowing greater access. It also decentralises support for R&D, allowing world wide capacity building. Finally, it has the benefit of giving freedom to design incentive structures to encourage R&D that addresses public health priorities and optimise therapeutic benefit.

There are already a number of direct funding initiatives in existence, including: the Medicines for Malaria Venture (MMV); the Global Alliance for TB Drug Development (TB Alliance); the International AIDS Vaccine Initiative (IAVI); and the Drugs for Neglected Diseases Initiative (DNDi).

The R&D fund approach supports ‘intermediators’ who are free to choose between different models (prizes, direct funding, open source). The continued funding of intermediators depends on their performance, while the support of intermediators could be decentralised, for instance through health insurance companies being given responsibility to contribute to R&D by picking an intermediator.

These ideas were developed at the World Business Council for Sustainable Development Project Dialogue on Intellectual Property Rights (2001-02), the Aventis Scenarios Workshop on Sustainable Health Care (2002), and the Rockefeller Foundation Workshops on Collective Management of Intellectual Property (2002-03). They were developed by Tim Hubbard and James Love, Director, Consumer Project on Technology (CPTECH) and followed discussions with many individuals in Médecines sans Frontières (MSF), OXFAM, Health Action International (HAI) and Third World Network (TWN).

Tim Hubbard then put forward three ideas from his experience as a scientist. First, knowledge based products can be delivered in the absence of intellectual property. The Human Genome Project that finished the human genome sequence, for instance, was achieved early, under budget and at a higher quality than originally planned. Yet it was done with academic salaries and no profit motive. Instead, it was underpinned by a strong structure of line management, with clear goals and regular planning meetings, together with weekly conference calls between grant holders and funders. This was augmented by a competitive atmosphere between Sequencing Centres, operating within a framework of open data and information exchange.

The second idea from Tim Hubbard’s experience as a scientist was that openness has benefits: less hassle; reduced duplication; driving progress forward; and exposing errors. Furthermore, the effect of restrictions on access to biological data is that, since biology is too complex for any organisation to have a monopoly of ideas or data, when a company starts a new project, it quickly discovers that most research is being done elsewhere. If blocks of biological data are held privately, even if access is paid for, companies miss out on the analysis that would be published by other scientists if they too had access to this data. Alternatively, the more people analysing a block of data within an ‘open source’ environment, the more valuable it is.

The third of Tim Hubbard’s ideas from his experience as a scientist was that patents have fewer benefits to society in today’s scientific age and can have negative side effects. Disclosure is less important since, with so many scientists, ideas occur to many individuals, often simultaneously. Credit should be given to those who disclose these ideas first. Patents, on the other hand, are mainly used as a means of industrial regulation to enforce the payback of upfront research.

The consequence of patents for medicine can be demonstrated by the case of breast cancer, where international patents were granted to Myriad genetics covering BRCA1 and BRCA2 breast and ovarian genes. As a result of the patents, the Myriad test is expensive (Euros 990 or $122). Cheaper tests have

been developed, ranging from Euros 122 ($107) to Euros 689 ($605), but these are blocked by the Myriad patent and cannot be used. The paradox is that much of the work on which the Myriad patents are based was carried out in the public domain.

Recent studies, such as The Royal Society Report 'Keeping Science Open: the effects of intellectual property policy on the conduct of science' (published on 14th April 2003) and the report of the Commission on Intellectual Property Rights (published on 12th September 2003), have concluded that patents can have harmful side effects on research and access.

Moreover, there are 'thicket' effects of patents with, for example, more than 100 patents related to a single antigen that is a possible candidate for a malaria vaccine. The possible solutions to this problem are to make compulsory licensing easier and less costly, or to create pools of essential patents to which all have access. Solutions like this can be seen elsewhere, for instance in the aircraft patent pool at the beginning of the 20th century, where the fee paid per aircraft was lowered from $1000 to $200 then $100 with a $2 million ceiling.

In conclusion, Tim Hubbard said that he could sum up his experience as a scientist in the following way: first, knowledge based products can be delivered in the absence of intellectual property; second, there are many benefits of openness; and, third, there are many disadvantages of patents.

Joseph Straus, Managing Director of the Max Plank Institute for Intellectual Property, Competition and Tax Law, Munich

Joseph Straus began by saying that the statement ‘knowledge freely available is the best basis for innovation’ is a doubtful statement. He said that everything is relative.

Intellectual property rights should be considered within the meaning of Article 27(2) of the Universal Declaration on Human Rights, namely that everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

But are there conflicts between intellectual property rights and other human rights? Do intellectual property rights marginalise the public domain?

Intellectual property rights are not an end in themselves. Rather, they relate to a means of economic policy: incentive, to reward, to disclosure, to protection of investment to innovation. IPRs create exclusive rights, but these are limited in time to 20 years. Other human rights, such as the sharing of scientific advancement and benefits, can materialise only if the latter are generated.

So are IPRs marginalising the public domain? In practice, 85 to 87 per cent of new publicly funded basic biotech research results are published, that is to say released into the public domain and made available on a free of charge basis for use and further development, without proprietary rights

As for the TRIPS Agreement, it is something of a marriage of convenience, guaranteeing market access in return for adequate protection of IPRs. But all parties to the TRIPS Agreement must meet their obligations if it is to have the intended outcomes.

TRIPS has had positive outcomes for developing countries, with transfers to India, China and Taiwan, not only in terms of locating production facilities in these countries, but also in terms of locating research and development facilities there. These are regions with low labour costs, adequate standards of education and stable political systems. Therefore, if these prerequisites are in place, there will be clear shifts in favour of developing countries as a result of the TRIPS Agreement. In this respect, intellectual property rights are the only means for recovering the costs of knowledge innovation and securing jobs. But there needs to be a balanced system.

A balanced system involves a strictly examined scope of protection commensurate to the contribution to the state of the art, together with limitations, for example in relation to a research exemption and compulsory licences. Adequately balanced, these elements can provide a basis for the sustainable flow of new research results.

In conclusion, Joseph Straus said that it will be important in the future to avoid the erosion of intellectual property rights through the dilution of TRIPS, but that the TRIPS Agreement was not a pioneering idea designed to rectify the

results of the colonial past and secure future prosperity. Instead, TRIPS is concerned with the removal of trade barriers, the acceptance of new competition and the nurturing of IP culture, namely respect for human creativity as the very basis of all progress. Finally, he called for the removal of trade barriers and the acceptance of a new spirit of cooperation, including a respect for creativity.

[The Moderator announced that questions to the panellists would be reserved until the end of Panel 4]

PANEL 4: OUTLOOK TO THE FUTURE OF TRIPS: HOW TO ENSURE AN APPROPRIATE IPR SYSTEM IN A GLOBALISED ECONOMY?

Moderator: Lars Anell, former Ambassador of Sweden to the WTO, Chairman of the Uruguay Round Negotiating Group

James Mendenhall, Assistant USTR (responsible for IP)

James Mendenhall said that it is not possible to disassociate intellectual property rights from wider issues. He identified two trends: first, that computer-related technologies and the internet have created new issues, and he asked: how do you ensure that the benefits for innovation remain? Second, he said that the interconnection in global markets in terms of production, distribution and research and development created benefits for developed and developing countries alike.

James Mendenhall then said that he would turn to the globalisation in counterfeit and pirated goods. He said that industries in developing countries were benefiting from intellectual property rights, such as the movie and software industries in India and, in China, the white goods and software industries.

With respect to access to medicines, pharmaceutical companies had taken steps to differentiate prices. Microsoft had also recently introduced price differentiation while, in the music industry, pilot studies on price differentiation are underway. There is a need to respond to public pressure and the key question is: how should differentiation operate in a globalised world? Intellectual property should be a stimulus for innovation and economic growth, while counterfeit products bring with them health and safety problems.

We are now moving into the next phase of TRIPS because, without enforcement, benefits will not accrue. There is a need for flexibility and it is necessary to ask the question: are the rules sufficiently flexible and what additional flexibilities need to be put in place? Having a common baseline is not necessarily a bad thing, but the question is: where should the baseline be set? Exceptions to TRIPS should and could be made but the baseline still needs to be put in place.

TRIPS is not static: it contains living rules, for example, in the form of the recent WTO Decision on TRIPS and public health, which demonstrates good governance. The amendment process must capture that argument. The United States, for example, is currently working with Canada to make sure that the US does not stand in the way of generic drug producers in Canada that are providing medicines for export under compulsory licenses.

In relation to access to genetic resources, there needs to be a full and open discussion to grapple with the issues involved, but that the forum for this discussion has yet to be agreed. In conclusion, James Mendenhall said that

intellectual property rights are currently in a state of flux in the global economy.

Thierry Sueur, Air Liquide/UNICE

Thierry Sueur said that UNICE consider the TRIPS Agreement to have been one of the fundamental reasons for the success of the Uruguay Round of multilateral trade negotiations in the sense that what was required was a level playing field for the protection of intellectual property rights. However, the real value of TRIPS will become apparent only after full implementation by all WTO Members.

Enforcement of intellectual property rights needs full implementation. This is in everyone's interest and experience and best practice must be exchanged in this respect. Industry needs to focus on further education to assist developing countries in meeting their obligations.

In conclusion, Thierry Sueur said that the route from patents, to growth, innovation and progress is well established and it is difficult to know how we would do without patents. He said that there are many flexibilities in TRIPS that are not talked about, for example patentability criteria and, in terms of intellectual property education, industry should have some responsibilities in terms of helping small- and medium-sized enterprises and developing countries.

John Barton, Professor Emeritus of Law, Stanford University, former Chairman of the UK Commission on Intellectual Property Rights

John Barton began by saying that what is required globally is patent harmonisation, but the question was: what system? He said that all reports, such as the US Federal Trade Commission in late 2003, state that there is a need to be careful to have a high standard of inventive step, a research exemption and revocation for wrongly issued patents. In terms of which institution should be responsible for patent harmonisation, John Barton said that it should be WIPO rather than the WTO. He then asked whether, in the case of developing countries such as India and China, there is the option of imitation as a means of achieving technological progress and economic development, as the US did during its period of development. He said that, in his view, current arrangements favour foreign direct investment over indigenous industries.

With regard to the role of patent portfolios, cross-licensing or reciprocal decisions not to sue have a role to play, and that use of the latter mechanism for developing countries needs to be explored further.

With regard to future action, there are two priorities:

1. Can we encourage the enhancement of the information commons? Might the WTO reciprocity process assist in overcoming nationalism, for example in terms of improving access to publicly funded research?
2. Given that TRIPS is not a traditional free trade agreement, how do we know that it is working? Why, for example, is there no data on licensing fees, research and development levels, or creative industries levels?

In conclusion, John Barton said that improved data can assist in making better judgements about how the system can be made to work better in the future.

Kevin Watkins, Head of Research, Oxfam

Kevin Watkins said that he intended to focus on the public health debate. He asked: why is there a link between patents and public health? The answer was that there is a set of rules at the heart of the linkage between ill health and intellectual property. This also raises issues about global governance and fairness and about WTO legitimacy.

The TRIPS Agreement was introduced at the behest of the United States and the pharmaceutical industry in particular. It is not in the best interests of technology importers in developing countries. Over time, it will be necessary to go back and have a fundamentally new agreement.

Kevin Watkins then set out the public health problems facing developing countries and said that public pressure and government litigation can result in price reductions by pharmaceutical companies (for example, as Bristol Myers Squibb has been forced to do in Thailand).

The business model for pharmaceutical companies is to have high value drugs, to charge what the market will bear, and to concentrate on drugs for Northern diseases. He said that the solution was for compulsory licences to be widely exploited without political pressures to ratchet up intellectual property protection via TRIPS-plus trade agreements. However, there were problems in setting up compulsory licensing arrangements, particularly due to the possibility of costly litigation for developing countries.

There is, therefore, a need for technical support from the European Union to assist developing countries in the use of compulsory licence provisions.

In conclusion, Kevin Watkins said that there were dangers associated with TRIPS-plus agreements. He said that Northern governments need to show good faith, and that developing country governments need to be encouraged to use compulsory licensing provisions. Above all, he said that mechanisms were needed to ensure access to medicines for the poor in developing countries.

QUESTIONS TO THE PANELLISTS FROM PANEL 3 AND PANEL 4

Lawrence Lessig seems to infer that the struggle against piracy is against heroic civil disobedience. This glamorises and justifies piracy, which is, after all, an illegal behaviour.

In response, Lawrence Lessig said that the existing system of regulation is producing extremism by those who think that they should violate the law and that the law should be ignored. An appropriate response, he said, would be to find the right balance in the digital age, not waging war to pacify the enemy, namely those engaged in piracy.

Why insist on strong provisions rather than footnotes to the TRIPS Agreement for the WTO Decision on access to medicines of 30 August 2003?

In response, Geertrui van Overwalle said that she suffered from experience with EU law and the binding effect of recitals. She said that there was a need to prevent scholars arguing over the binding effect of an annex to the TRIPS Agreement.

How should the review of the TRIPS Agreement take account of the Convention on Biodiversity and the Berne revisions? Also, how can a new measure create genuine competitiveness?

In response, Lawrence Lessig said that there was a need for good economics in the TRIPS debate.

Thierry Sueur said that industry has seen no problems with patents for software over the last 20 years.

Given that software code is mainly text, is not freedom of expression therefore restricted by patents?

Laurence Lessig said that this was not the case, the problem of the IP is just that it relies on bad economics.

Given that least-developed countries now have exemptions until 2016 under the WTO Decision of 30 August 2003 with respect to the introduction of pharmaceutical product patents, what strategic plans should be put in place in the interim period to assist with implementation of the TRIPS Agreement?

In response, James Mendenhall said that the date of 2016 is without prejudice and that least-developed countries can ask for additional time. He said that there were no plans to alter the 2006 deadline for least-developed countries to meet other obligations under the TRIPS Agreement. James Mendenhall said that the developed world stands ready to offer technical assistance and that tens of millions of dollars had been spent on packages for technical assistance.

Kevin Watkins said that TRIPS was a bad agreement for Africa because it increased the rent of international technology transfer and that the litmus test will be how new compulsory licence rules are rolled out.

Is it not the case that Article 39.3 TRIPS and the existence of TRIPS-plus agreements makes it difficult to reverse engineer?

In response, James Mendenhall said that reverse engineering was acceptable in software, but not in other areas.

Might the proposed review of TRIPS lead to general global rules on intellectual property enforcement?

In response, James Mendenhall said that what may be discussed is best practice and the exchange of information rather than substantive disciplines. He said that it is time to have a high level discussion on enforcement in the TRIPS Council and that there were already on-going bilateral discussions about this. It is, he said, time to bring those discussions together. John Barton said that, especially in relation to patents, what was needed was appropriate compulsory licensing arrangements, research exemptions and appropriate patent infringement rules, but that this was problematic even in Europe.

Could Kevin Watkins justify his claim that there is a link between patents and access to medicines?

Kevin Watkins said that a major cause of death is the fact that patients stop taking drugs due to lack of affordability, but that access to medicines is not only a question of price, but also of accessibility.

Could Tim Hubbard explain his proposal to substitute market-led decision processes with a publicly driven process?

Tim Hubbard said that decentralised innovation funds can compete and therefore avoid ineffective resource issues.

John Barton said that there is a need to focus on vaccines and not only on drugs to tackle diseases.

There is concern about the future of TRIPS and the lack of technical capacity to utilise flexibilities. Could the panellists respond?

James Mendenhall said that flexibilities can be used effectively and that technical assistance is available. In this regard, the US stands ready to help, he said.

Kevin Watkins said that alliances are needed between developing countries and that these alliances have not so far been seen as much as they could have been in the area of public health. Nevertheless, he said, there is the potential for cooperation between countries with generic drug companies, on the one hand, and Sub-Saharan African nations, on the other.

Thierry Sueur said that Air Liquide is surprised by the high number of minor innovations coming from everywhere – not just from developed countries. He said that, as markets became more global, product markets would also become more local, in doing so meeting local demands.

How can TRIPS-plus agreements be justified?

James Mendenhall said that the issue was one of protecting of US interests. With regard to Article 39.3 of TRIPS, this was simply an issue of clarifying the period of data exclusivity as it is understood by the United States. He said that this did not hinder public health issues.

With respect to access to genetic resources, why is the EU not opening this debate and trying to obtain breeders' exemptions?

Tim Hubbard said that access to genetic resources affects all of us.

Geertrui van Overwalle said that the FAO International Treaty on Genetic Resources for Food and Agriculture could lead to the re-introduction of global commons.

Vandana Shiva said that public sector research and development and the results of farmers' own work are preferable to patents. The latter leads to a threat to global food security, she said.

Lars Anell, the Moderator, then asked the panellists of Panel 3 and Panel 4 to sum up their thoughts.

Geertrui van Overwalle said that she thought that patents on genes might be an historical mistake with no way back, and that there were important issues about patents and public health.

Lawrence Lessig said that extremism in the fight against piracy is creating unintended costs in terms of preventing the spread of progress and creating cynicism about intellectual property rights. He said that balance is the key for property rights.

Tim Hubbard said that there is a danger of dogma and that we must not kill off innovation. He said that there was therefore a need to look at alternative methods such as open source to support innovation.

John Barton said that there is an institutional bias that favours the IP owner and that this needs careful consideration. He said that developing countries need advice but that the TRIPS Agreement is not the only issue. Other issues were patent and copyright harmonisation, and there is therefore a need to keep up-to-date on this.

James Mendenhall said that what is required is discussion, a period of taking stock and ensuring that TRIPS is fully implemented. He said that there is a

need to explore what can be done to identify appropriate flexibilities for developing countries. There is, he said, a need to regularly monitor the impact of the TRIPS Agreement and take stock.

Thierry Sueur said that patents are a fantastic basis for innovation and that there is therefore a need to start from accurate information. He said that patents are a fight against secrecy.

Kevin Watkins said that TRIPS is about getting the balance right. He said that the key element in the Bristol Myers Squibb case in Thailand had been that the outcome was that public health must not be treated like a commodity. He said that political commitment was the key.

Vandana Shiva said that there is a need to review Article 27(3)(b) under the Article 71 review procedure of TRIPS because the existence of Article 27(3)(b) threatens the legitimacy of the TRIPS Agreement. She said that there is a need to revisit whether industrial property is appropriate to life forms and genetic resources and that there must not be systems that reward biopiracy and theft.

Concluding Remarks from Pascal Lamy, EU Trade Commissioner

Pascal Lamy said that the conference had dealt with controversial issues. It would be an exaggeration to say that the debate had led to clear conclusions that are shared by everyone. Rather, the conference had been an occasion to acquaint ourselves with the wide variety of opinions that exist in this area and, perhaps, to adjust our positions. Nevertheless, he said that he ventured some conclusions on the basis of the four questions that he had put in his opening speech.

1. Is the balance underlying TRIPS still valid?

All agreed that balance is a key issue. His impression was that many panellists agreed that, by and large, the balance struck in TRIPS is correct. This balance has sometimes been misinterpreted or misrepresented, but we have to keep this balance right: TRIPS mandates compliance and balance.

However, the essential conditions to get the balance right lies in the possibility to exploit the key flexibilities in TRIPS. In this context, most panellists considered it unfair that developing country Members are sometimes put under pressure to adopt substantive TRIPS-plus standards that are not adapted to their level of development. Flexibility should not be taken away through that backdoor. TRIPS was viewed by many as a shelter against bilateral approaches and TRIPS-plus standards threaten the very viability of TRIPS and render enforcement more complicated.

Many panellists also recalled the basic objective of IP: to stimulate innovation and creativity. Claims have been made that IP may, in certain circumstances, act as a barrier to further innovation and creativity or may even not be based on good economics. Where this is the case, this problem should be addressed upfront, otherwise the legitimacy of the IP system is threatened.

New methods of dissemination of knowledge, such as open source, in so far as they prove economically effective, should be actively explored.

It has also been said that there is indeed a risk of IPRs marginalizing the public domain. But solutions appear to exist. Suggestions have been made: cross-licensing, patent pools, compulsory licensing, blanket licence or even entirely new systems: what is striking is that none of them are prohibited by TRIPS.

2. Which policy goals or technological evolutions would justify changes to TRIPS?

It is important not to forget that TRIPS itself mandates reviews and further negotiations, as confirmed in Doha. Take, for instance, geographical indications or the review of Article 27.3(b).

Many reasons have been invoked for reviewing TRIPS. The main reasons are: technological developments and resolving conflicts between intellectual

property rights, on the one hand, and public interest or human rights, on the other.

Indeed, there have been technological developments in the last 10 years which may warrant a closer look at TRIPS. And there is no doubt that human rights and public interest must be part of the balance in TRIPS, as confirmed by Articles 7 and 8.

There are also issues linked to collective rights: geographical indications, biodiversity, farmers' rights, or traditional knowledge. And last, but not least, ethical reasons have been invoked with regard to life patents.

Finally, the proper implementation of the enforcement provisions of TRIPS is an important, and justified, source of concern. Full implementation of TRIPS is key. What is there should be genuinely enforceable.

TRIPS has not halted industrial counterfeiting and so we need a strategy to do better. In this respect, pressure and threats alone do not work. The best way to achieve compliance is through 'friendly' input: discussion, capacity building and technical assistance. These ideas have been largely shared by developing country representatives.

3. Global governance in the field of technology and knowledge?

This is probably an issue that has not been sufficiently addressed in this conference, at least not directly. But to boost innovation in the developing world, and certain types of research in the developed world, IP alone will not be sufficient. Serious structural reforms are necessary to enable developing countries to contribute effectively to innovation. They are also needed at international level.

Interesting proposals have been made as regards the creation of new models for boosting research and development or separate systems for non-commercial innovation or creativity.

If we are serious about the objective behind IP, we should look at these proposals with a benevolent eye and further examine them. Such alternatives can be complementary and co-existing with the IP system, not a substitute for it.

4. How to improve the ability of developing countries to benefit from intellectual property rights?

Can IP act as a boost for development? Many have said that it can, although this applies mainly to the emerging developing countries. It must be accompanied by the appropriate policies and supported by technical assistance.

Reference has also been made to biased types of technical assistance which deny flexibilities, or to technical assistance that stops when enforcement

begins. This can be addressed by respecting two basic principles: first, efficiency (i.e. it must lead to effective enforcement) and, second, objectivity (i.e. fully inform the recipient country of available options, within the limits of TRIPS).

Implementation of TRIPS can be a win-win situation for developing countries if we focus on rights that are of most direct advantage to them, such as trademarks or geographical indications.

Developing countries have to be enabled to implement TRIPS in a 'pro-competitive' way, so as to better prevent the abuse and misuse of rights by right holders.

They must also be supported in fully implementing the Doha Declaration and the 30 August 2003 Decision. The EC is fully prepared to do that.

Synergies must be created among countries. Regional cooperation can maximise benefits and limit implementation costs. Good examples for this are OAPI and ARIPO in Africa.

As regards least-developed countries, it has been said that none of the LDCs today are today in a position to innovate and to benefit from IP. Since development and innovation go hand in hand, efforts should primarily go to development, transfer of technology and creation of domestic or regional innovation capacity. We also have to bear in mind the blatant lack of resources of the LDCs and poorest developing countries. Therefore, demands for the extension of the transition period for LDCs after 2006 will have to be looked at with a benevolent eye.

Conclusion

There is no doubt that TRIPS will remain a debated issue for years to come. It has shown issues that deserve to be pursued further. In the EU we strongly believe in the virtues of IP as an engine for creation and innovation. At the same time, we do not remain blind to the difficulties and challenges entailed by IP protection in certain areas and in certain regions in the world, especially in the developing world. Hence, there is a need to look at IP with an open mind and not be afraid to address shortcomings.

It is also important to bear in mind that, at present, we have the means to catalyse ideas and innovations in ways that are less dominated by the economy of scarcity. Systems of free dissemination and free-of-cost access may prove efficient in certain areas.

For EU trade policy, the challenge is to follow an approach that takes into due account the legitimate interest of industry *and* users, developed *and* developing economies, small *and* large enterprises, researchers *and* students, public *and* private goods. We must avoid lopsided and biased policies.

In conclusion, Pascal Lamy said that, when considering changes to TRIPS, we must continue to keep its basic purpose to mind. The purpose of IP, he said, is to enhance creativity and innovation for the economic and social development and welfare of all, and so must be the purpose of the globalisation of IP.