

Commission on Intellectual Property Rights

CONFERENCE

***“HOW INTELLECTUAL PROPERTY RIGHTS COULD WORK
BETTER FOR DEVELOPING COUNTRIES AND POOR
PEOPLE”***

TRANSCRIPT
Session 6: Medicines and Vaccines

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THE ROYAL SOCIETY
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SESSION 6: Medicines and Vaccines

Daniel Alexander: Chair, IPR Commissioner

My name is Daniel Alexander and I welcome you back to this totally uncontroversial session on medicines and vaccines. Before we turn to our excellent speakers, I want to make a couple of short remarks. When the Commission was set up last May, the debate in this particular area could probably be described as being in litigation mode. There were claims and counterclaims, mutual accusations of exaggerations of the benefits on the one hand and the cost on the other hand. I am happy to say that, whilst we don't in any way underestimate the strength of views or the strength of interests in this area, we are encouraged by a sense that we may be moving, at least, somewhat away from litigation mode and into problem solving mode. We are looking for common solutions with a way to ensuring that, at least in this area, IPRs remain, as they must always be, our collective servants and not our collective masters. The second point is that, as many of you will know, debate in this particular area is not really a new one, albeit that it now has a particular public prominence. A few weeks ago I was doing a case before a Mr Justice Laddie who, as you may appreciate, is not the easiest of tribunals to appear before and one must be very well prepared, so I was looking back through various materials to present the case and I found a report entitled "Reform of Patent Law" which is 25 years old, produced for the government of a developing country. There was a debate at that stage as to what reforms should be introduced, whether there should be compulsory licensing, crown use and so on. There had been extensive debate, Commissions set up and a report was prepared for Parliament. The report said it has to recognise that patent protection for pharmaceutical products was necessary to the existence of a research based pharmaceutical industry evolving new valuable remedies. It also said, in relation to certain powers that still exist in the developing countries' patent legislation, that there should be powers for the government to control price, that there should be a procedure that would entitle the government to make use of patented pharmaceuticals for the services of the health service with terms to be settled later by the court if necessary and there was a reference that if in context of the health service a patentee was abusing a strong market position to overcharge the government for the supply of patented products, the powers of the ministers were ample to deal with the situation, and those powers should be retained. That developing country was, of course, the UK, 25 years ago. Some people who have used the railways in this country may think that we should be making an application to extend our obligations for TRIPS compliance until 2016. We are, in any event, determined to learn such lessons as we can from the past. This particular developing country has found that IPRs are not incompatible with providing a good healthcare, albeit that there are a large number of other things that are required to do that. Equally, this country has found that effective regulation of the exercise of IPRs is not incompatible with a very vigorous and thriving research based pharmaceutical industry. We are seeking compromises in this area and, with the assistance of you all, seeking cross fertilisation from different fields as to what the optimal solutions are. Before I introduce the speaker from Pfizer, one of the points of cross fertilisation that one notes, bearing in mind something that a representative from Switzerland said yesterday, is that one can draw lessons from different areas. It strikes me that if there were a promise of IPRs of unlimited duration for particular indigenous groups

which didn't require recording, one would see Pfizer abandoning their headquarters in Manhattan very quickly and going off into a rainforest somewhere and setting themselves up as an indigenous group. May I now introduce Robert Mallett. He is a lawyer, a Senior Vice President, Corporate Affairs, Pfizer. He is a visiting professor of practice at Harvard, John F Kennedy School of Government. He has served in the US Government as Deputy Secretary of Commerce and has been in legal practice before that. He was a City Administrator and Deputy Mayor of Operations for the District of Columbia and we warmly welcome him to make his presentation.

Robert Mallett: Pfizer

I am uneasily aware that I am the only industry representative speaking here, looking out at many of our toughest critics and though I have only been at Pfizer for about nine months, I do represent it. It is the world's largest pharmaceutical company, I am from the United States, the richest country in the world and I feel a little like a lamb being led off to slaughter. While I always did believe that the lion and the lamb could lie down together, I believe that the lamb wouldn't get much sleep. I have been listening to this for two days and have not had much sleep. I am honoured to be here, yet I hope that some of you decided to take a picture of me before I started talking because after you have finished working me over, I want sometime to take an after picture. I have thought a lot about the subject of IP from several different perspectives. One as a lawyer, and now I am in the pharmaceutical industry. Amazingly, my views about the subject have remained reasonably consistent over the years. I have had an opportunity to see how the system really works and, in large measure, I have seen how it works from the point of view of very wealthy people in a very wealthy country who had a lot to protect. Most of the patents in the world are issued by the US, the European Union and Japan. I think, because the system has worked that way, that sometimes when we have this discussion we have a tendency to talk past one another – **tape change** we don't come to the table with the same degree of scepticism and we don't seem to believe the same things. I, for one, believe that IPRs serve as the fuel for genius. Genius mainly from my country and many other parts of the world are driven by the private sector. The private sector has delivered in large measure most of the medicines that we have today. I don't think that is a questionable proposition. Certainly the Government does lots of basic research in my country and other parts of the world, but companies, pharmaceutical companies, research-based companies, bring us most of the miraculous therapies we have today. There is a story that I read once about Winston Churchill when he was not the Prime Minister and he was listening to a socialist party candidate extol the virtues of a planned economy. The Labour Party member was going on about the virtues of a planned economy and the virtues of Government and he said that, as an example, the speaker mentioned that there had been a large population increase under the last three years of the Labour Government to which Sir Winston said "Wouldn't the honourable gentleman concede that the last statistic about population is the result of private enterprise." I like that story because I feel that it is our obligation not to simply impugn our efforts but to improve them. Private enterprise is not the solution to every problem, but it has created many admirable things. One of them is a battery of medicines that can save lives in that population that only a generation ago would have simply been unthinkable. The question the Commission is considering from the perspective of the pharmaceutical companies,

research based, is how do we maintain that model which had brought the world so many therapies and is sure to bring us more and still recognise that we have a critical role to play and a moral obligation to get medicines to people with weak healthcare and weak healthcare infrastructure. One simply cannot see the scourge of AIDS and look at the numbers and not want to do something about it. It would be impossible to see 28 million people on the continent of Africa with AIDS and not want to find a way to help. Yet, there are other diseases. AIDS is only one disease. What of the other so-called Third World diseases which effect the vast majority of the world's developing countries, malaria, tuberculosis, and many others. Of course, it is no accident that these diseases occur almost exclusively in poor countries. If we are honest at all with ourselves, one of the primary reasons we are having this rather engaged discussion today, or we are so focused on the healthcare gap between the developed world and the underdeveloped world, particularly in Africa, sadly is because of AIDS and AIDS became not just a Third World disease but became a Western disease and that we all had an opportunity to witness the cruelty of that disease and how it ravages lives. The old diseases are still there, we don't debate about those in the same way and they are still taking lives and many of them can be treated with medicines, which have been off patent for dozens of years. Yet the same dreary and fact statistics remain about those diseases. Now, this is one of the reasons that I am convinced in my professional and personal capacity, that these problems are not linked substantially to the protections that innovators are afforded in exchange for commitments to invest what they invest in R and D the treatment for cures. I know that some people in this room, incredibly, passionately believe that patents on pharmaceutical drugs are the reason that poor people lack access to basic medicines. I, of course, disagree with that. I wish it were as simple as that, because if it were this is a completely solvable problem. Poverty, that intransigent thing, the thing that we have been trying to cure for thousands of years in large measure is responsible for poor people not having access to drugs. I believe that we risk, very seriously, prolonging the intransigency that both the effected governments and developed countries have shown in addressing this problem, if we continue to define the problem as one chiefly having to do with patents and not poverty. I have a chart to show that South Africa spends only about 42% of what the UK does on its healthcare system. Brazil spends about 30% of what the UK does and Chad spends .02% of what the UK does on its healthcare system. The UK has 50 times more doctors that Chad, has twice the number of doctors for 100,000 people as South Africa. In a recent study by Harvard University researcher, Amir Attaran and Lee Gillespie White of the International Intellectual Property Institute published in the journal of the American Medical Association, concluded that patents are not a leading barrier to AIDS treatment in Africa. Why? Because most antiretrovirals are not patented in the majority of African states. Twenty-five percent of the 53 African countries surveyed do not have any patents on antiretrovirals. In the rest, an average of only 4 of 15 antiretrovirals are under patent. In fact, 26 African nations had no patents on 4 of them. No country had patents on all antiretrovirals. Except for South Africa, no country has more than 8 antiretrovirals under patent. Finally, given the number of drugs surveyed about 15 that were the gold standard treatment for AIDS and the 53 countries involved the potential existed for some 795 patents but only 172 actually existed. Going further, the Trade Association, which represents my company and many others, surveyed its member companies concerning the patent status as of 1 August 2001. Of all the pharmaceuticals used to treat other major communicable diseases that are prevalent in Africa, including opportunistic infections

association with HIV, tuberculosis, malaria, trypanosomiasis, sleeping sickness and diarrhoeal diseases, here is what we found. Opportunistic treatments, there are 27 drugs available, 66% of the countries surveyed don't have any patents for those drugs. No country has patents on all of them. TB, there are 11 drugs available, 94% of the countries surveyed do not have patents on any TB drugs. No country has patents on all TB drugs. For malaria, there are 13 drugs available and 95% of the countries surveyed don't have patents on malaria drugs. No country has patents on all malaria drugs. There are 4 drugs available for sleeping sickness and not a single country surveyed has patents on those drugs. For diarrhoeal diseases, there are 3 drugs available. Not a single country surveyed has patents on those either. In fact, what we know is, of the 300 or so medicines on the WHO's Essential Drugs lists, 98% of them are off patent. There are two points I want to be clear on. IP is of paramount importance to the research base industry and second, I believe that we can conquer AIDS and other diseases afflicting the Third World, but we can only do so if we are willing to attack all of the elements that make up a healthcare system, all of the elements, not one portion of it. As Justice Laddie said yesterday, it is obvious that without some IP, the pharmaceutical industry would simply have no incentive to invest the amount of money that we do, and we wouldn't get many drugs. You know all the statistics about our research and many of my colleagues who are here today from the pharmaceutical industry understand the role that we have to play. We believe that the treatment for AIDS and other deadly diseases cannot rest on the shoulders of one industry. The solution does not fall within the four corners of the TRIPS Agreement. That, I'm afraid, is the direction that many people want to take this discussion and debate and it's the wrong direction and it has identified the wrong enemy. We will only succeed in conquering AIDS and other kinds of diseases when we address all of the elements that make a healthcare system work and to know that there are many different models and strategies we can use to help solve the problem of disease. We believe in partnerships and I think that is very clear. At Pfizer we concluded that the best way for us to offer service and to meet our moral obligations is to donate eye drops. That's a strategy we have chosen, because we decided that no matter what we charged, no matter what it is, it turned out to be too much. The best thing to do was figure out how to help build infrastructure and donate them. There are companies that have chosen other ways to do it, without changing a single word in TRIPS. Companies are wholesale rewriting IP rules, some companies are offering voluntary licensing and medicines at cost or below cost, they are providing medicines free of charge and helping to rebuild an infrastructure or build an infrastructure where none exist. One example I must bring to your attention. We have been working with the Government of Morocco to eliminate trachoma. We have been doing it for about 4 years now. We have seen a 78% drop in the number of infections in trachoma in Morocco. We see the end of the tunnel for eliminating that disease. That is a strategy that works. It is a donation strategy. I believe that we can figure out ways to conquer diseases in similar ways. The two major enemies to disease in the Third World that we should be focussed on, on the problem of access, are infrastructure and financing. Infrastructure and financing are the two areas where we need to be concentrating our efforts. Meanwhile, while we are doing that and thinking of solutions about that, developing countries should begin to take a more aggressive advantage of the willingness of research based companies to provide their medicines through partnerships that work. Thank you.

Daniel Alexander

Our next speaker is Francisco Cannabrava who has been a diplomat at the Permanent Mission of Brazil to the UN and the WTO since 1999. He is a delegate of Brazil to the TRIPS Council and to WIPO. He was previously at the Trade Policy Division of the Ministry of Foreign Relations in Brazil.

Francisco Cannabrava: Permanent Mission of Brazil to the UN/WTO, Geneva

I would like to thank the Commission for inviting me to address this issue. I should clarify that I am speaking here today on my personal capacity. My views do not necessarily reflect the official position of the Brazilian Government, although I think that we agree on quite a number of issues. Last year a number of initiatives in international fora addressed the relationship between IPRs and Public Health Policies. As you may know, there were important resolutions approved by the World Health Assembly, one very important resolution at the UN Commission on Human Rights, at the WTO Ministerial Conference in Qatar in November there was also a declaration that I am going to focus on particularly today, not to mention the withdrawal of the suit by the pharmaceutical industries against the South African Government and last but not least the withdrawal by the US of the panel requested by that country against the Brazilian Patent Laws to WTO. All these elements as a whole strengthen the concerns by the public opinion over potential negative implications of IPRs on the potential negative implications of those IPRs on national Public Health Policies. In order to address more directly the issue of this session, I would like to focus particularly on the WTO Ministerial Declaration on TRIPS and Public Health and also the future work related to the scope of that declaration at the WTO. It is safe to affirm that the declaration fulfilled the immediate negotiating objectives of developing countries and this was quite a team effort among developing countries. It is definitely a good example of how developing countries with great support from NGOs can achieve meaningful results in the discussion. The negotiating objectives of developing countries were, since the beginning, to clarify the relationship between the TRIPS Agreement and Public Health Policies. At search, the declaration does not modify the text of the TRIPS Agreement, but it does provide unambiguous guidance from the highest WTO body for future decisions by the WTO Dispute Settlement Body against narrow readings of the flexibilities of the TRIPS Agreement, such as compulsory licences and parallel imports. This, in my view, is the most significant impact of this declaration. The programme for this session of the conference poses the question, How and in what ways are IP rules and practices important for better health, particularly of poor people. I think there are three important elements that are useful to answer. One is related to the element of innovation of new drugs, one related to the need to level the playing field in existing IP standards, particularly of the TRIPS Agreement and finally the need to fulfil to objective of transfer of technology. Concerning the element of innovation in principle no one will challenge the relevance that IPRs, patents in particular, may have as an instrument to encourage the development of new drugs. There may be evidence to the contrary but I am not going to enter into that discussion right now. I am going a step beyond that, assuming that quite a number of countries already has IP legislation in place. The thrust of the recent developments in international fora such as the WTO, the WHO and the UN Commission on Human Rights, however, if not to

question the relevance of IPRs as a whole but to ensure that they will not be placed above or certainly not in same footing as overarching public policy objectives, such as public health. The Ministerial Declaration on TRIPS and Public Health for instance purely dismisses the approach that IPRs amount to sacrosanct, absolute or Devine rights. On the element of the need to level the playing field of existing IP rules, the TRIPS Agreement allows Governments to take measures to prevent abuses of rights and the core paragraph of the Declaration on TRIPS and Health clarifies that TRIPS does not and should not prevent members from taking measures to protect public health. This element of levelling the playing field is very much related to discussions we had in other panels and also in the last panel on the need to balance rights and obligations. Yesterday someone made an interesting intervention, "We keep talking about IPRs, what about IP obligations?" I think that is very much in line with the discussions on "In which context are we supposed to discuss IPRs and what are the safeguards that we have to apply when a developing country is going to provide exclusive rights for a company to sell and commercialise products haven't the monopoly of that protected product in its country. This has to be seen under a balanced approach. In this regard, paragraph 5 of the TRIPS and Health Declaration clarifies that TRIPS should be interpreted in the manner supportive of members' rights to use to the full the provisions of TRIPS, which provide flexibility. Compulsory licenses are among the most relevant tools available for governments to prevent abuses of rights and to ensure access to affordable medicines. Naturally, there is also a role for developing countries to explore this kind of flexibility. Part of the reason why developing countries haven't resorted so much yet to the use of compulsory licences is also related to the fact that the varying protection of comprehensive and standards of IPRs is new. I think time will tell when developing countries will start to use these safeguards but Brazil has an interesting experience in this respect, taking into account the examples of last year when we were having discussions with Merck and Rush regarding two antiretrovirals and we made it very clear that if the extremely high price that was being charged was not brought down, the only possible solution would be to issue a compulsory license. I believe that the final result was a win-win situation in which the patent was protected after all and the price was brought to a reasonable level that would ensure the sustainability of the Brazilian HIV programme. I believe that the element of persuasion of the compulsory licences is also an element to be taken into account. The third element I will address is transfer technology. I cannot emphasise enough the importance of this, given that it is actually one of the main objectives of the TRIPS Agreement. Unfortunately, it doesn't seem to be given enough importance in the discussion on how IP rules can work in favour of public health. At the TRIPS Council last year developing countries expressed a view that local production of pharmaceuticals were never economically feasible. It is extremely important to ensure that pharmaceutical products are more readily available and at more affordable prices. Sustainability of access to pharmaceuticals and the development of local expertise are also key factors of transfer of technology. I was very happy in this respect to hear the intervention of my colleague, Edward Chisanga, on his proposals on how to address this issue regarding least developed countries. They are absolutely in line with the position, which developing countries have taken in this regard. The regular exercise of IPRs, patents in particular, should result in transfer technology. When the titleholder fails to transfer technology as a result of an abusive conduct, governments have the right to make use of compulsory licences so as to ensure that others may actually fulfil the objective of TRIPS by the local

manufacturer of drugs. This is one important element of how IPRs can benefit public health. Obviously, countries with insufficient or no manufacturing capacity, particularly in the pharmaceutical sector could face difficulties in making effective use of compulsory licenses. By recognising this problem, WTO ministers have instructed the TRIPS Council to find an expeditious solution to it before the end of this year. Developing countries are still in the process of elaborating their proposals on this but it seems very likely that the solutions envisaged might require an amendment of article 31f of TRIPS or an authoritative interpretation based on article 30. This is a very important element to be taken into account by the Commission. Unfortunately there is very little time left and I will not be able to give an extensive description of how these solutions could be addressed. I hope there will be questions on these two elements so that we could elaborate on them but, as you know, article 31f establishes an inbuilt flexibility allowing countries to export products arising from compulsory licenses but there is a limitation that this should be predominantly for the domestic market of the country. The alternative solution would be based on article 30, but then we still have to consider under which modalities could an authoritative interpretation be drafted in order to find a solution to this problem, but in essence the solution could be that third parties could manufacture an export for another country, an importing country, with no or limited manufacturing capacity. All this has to start from the assumption that transfer of technology is the primary goal of IPRs, so the point of this discussion is not to favour the element that IPRs should necessarily be fulfilled by the mere importation of products, that is not the approach that developing countries are going to look for. What is necessary to ensure sustainability and to make sure that the objectives of the TRIPS Agreement are going to be fulfilled in the sense of social and economic wealth is certainly the element of transfer of technology and this has to be an integral part of the discussion. I could spend a whole day discussing other issues on how the TRIPS Agreement could affect public health, even taking into account the Declaration on TRIPS and Public Health. Just to mention briefly the issue of Protection of Test Data, which was left out of the Declaration, but many developing countries are still very much interested in that discussion. The issue of non-violation is a very technical issue, but with very important consequences. This is most likely for further discussion either under the review of article 71.1 that is the Substantive Review of the TRIPS Agreement or under the Implementation Discussions at the WTO. These implementations are ones related to rebalancing the WTO agreements and where developing countries have very important proposals. To conclude, although we have achieved quite a satisfactory result in Doha the battle is definitely not over. We do have a lot of ground to cover. The fact that we now have this Declaration allows us to try to level the playing field in quite a number of areas of the TRIPS Agreement. At a political level, there was a reference to the importance of China in this discussion. I think that is an extremely welcome development at the TRIPS Council and we hope that China will come and be a very important participant in this discussion. I hope we will continue our discussion with the questions.

Daniel Alexander

Our last speaker is Sisule Musungu. He is a lawyer and consultant on TRIPS at the South Centre in Geneva. He is an advocate of the High Court of Kenya and a

member of the Law Society of Kenya. He has been a member of the Kenya Coalition for the Access to Essential Medicines since 1999.

Sisule Musungu: South Centre

I would like to thank the Commission for giving me the opportunity to speak. Like Francisco Cannabrava, I would like to clarify that my views are personal views and would not necessarily represent the position of the South Centre on developing countries. We have been talking about vaccines and medicines for about 3 years now. Obviously it is going to continue for several years to come. I think it is agreed that there are many barriers to health for poor people and I don't think that is what we are here to talk about. The question is very simple. Are IPRs relevant to aid the development or access to pharmaceuticals? That is the contribution that the Commission needs to make to the overall picture of other barriers and, therefore, I don't think the question to examine here is how much money we will need to build an infrastructure in Pumulanga in South Africa, because that is another question. We are talking about the TRIPS Agreement, but not just the TRIPS Agreement. One practice, which has been mentioned in Amir Attaran's study, is that pharmaceutical companies have the practice of not portending in countries that have spent money to establish systems. Fifty African countries have systems where pharmaceutical companies will not take time to portend there. Look at the TRIPS Agreement for example, and the imbalances that are imbued there. I think it is generally agreed that the negotiations were not fair. The technical assistance given to build the systems does not allow countries to look critically at their development needs to determine how to use their flexibilities or even how to conceptualise an IPR system. The best example is the francophone system in Africa, which was given technical assistance to revise the 1977 Bangui Agreement to comply with TRIPS. What they were not told is that LDCs have transition periods and could exercise this and the agreement was revised for the whole 15 countries and 12 of them are LDCs. Moving to the Doha Declaration and process issues. Why did it take a whole year for the WTO to say that countries are allowed to use compulsory licensing? There was an enormous amount of energy, resources depend on that process and I am sure Francisco will be engaged for several years in another debate to solve the problem of countries without manufacturing capacity. Those are problems that are focusing energy in the wrong areas. We need to introduce infrastructure, but we cannot build infrastructure if developing countries have to spend four years trying to establish that they are entitled to protect public health. It leads nowhere. In terms of the export issue and compulsory licensing the WTO wants to find a solution to the problem for countries without manufacturing capacity. As we consider this, we need to look, not just at countries with patent systems but also consider countries without patent systems and the whole range of scenarios that are there to solve the problem. We need to look at immediate problems, which is access for HIV for example. Also longer-term problems in terms of are we looking at building capacity in those countries eventually or are we going to maintain capacities in the few developing countries that have the capacity. I want to talk about the tiered pricing schemes that are being exercised in some countries. In Kenya, for example, there has been a tiered pricing scheme. I think the agreement between the companies and treatment centres that benefit from that was given to the Commission when it visited Kenya. One of the conditions in that agreement which may or may not have relevance in this

debate is that the people who access that tiered scheme have to agree that price is not a factor in access. I would be interested to see what the Commission has to say about such an agreement, which is a mechanism which we are told will be used properly to reduce prices. Last week, Pfizer donated the diflucan to the Ugandan Government. Interestingly, the Pfizer patent on diflucan in that region is running out in April. The donation has been given for two years. There are four generics waiting for the patent period to expire so that they can introduce their products. What has effectively happened is to kill those generic manufacturers, because the donation saturates the market, recovery has already been made by the company. How then does that donation operate? What long-term structure are we looking at with donations? East African Editorial raised the issue that the donation is limited to private treatment centres. It is a good gesture, but how is that going to be accessible and useful. The UN has been doing some work in terms of human rights and the relationship between human rights and trade rules. One area of focus has been public health and TRIPS. If you look at the conceptualisation of the issues, there are certain articles in the Human Rights instrument, Article 27 of the Universal Declaration of Human Rights, particularly Article 15 of the Covenant on Economic, Social and Cultural Rights. I appreciate why that Covenant has not been used much, because the philosophy of 1966 was that those were not human rights and therefore we have not seen this in the development of the IPR system. I would like to encourage the Commission to consider the conceptual and opinions of Article 27 of the Universal Declaration of Human Rights, which deals with IPRs and particularly Article 15 of the Covenant on Economic, Social and Cultural Rights in looking at the balance we want to achieve. The benefit to society would be the end product we would like to see. That way of conceptualising the issue might be useful in terms of developing countries trying to think about what they want to do. Finally, I would like to discourage the Commission from arriving at the conclusion in this debate about infrastructure and resources. If that is the conclusion, I think you will have what the title says, "People are poor." So don't make a recommendation that people are poor, because we know that. We are trying to solve their problems, not to tell them that they are poor.

Roy Widdus: IPPP, Global Forum for Health, Geneva

To emphasise the infrastructure question, I would like to give an example of a study that was done with the donation of nevaripine for prevention of mother to child transmission. Beringer Ingleheim made the offer. With the German Aid Agency they did a study of the full cost of implementing a donation of nevaripine. Even if they had bought the drug the full cost would have been only 2% of the full cost of implementing the whole of the health service as necessary for that to be used properly. I know there is a certain amount of happiness with the creation of this global fund for AIDS, TB and malaria, but I think we need to be realistic that it isn't a massive infusion of new financing. If we look at the amount Kofi Annan said was needed for AIDS which was 7 to 10 billion, the amount that has been raised from the International Aid Community has only reached about 1 to 2 billion so far, so I think there has to be a lot more pressure on bilateral agencies. Finally, I wanted to commend the speaker from industry. There has been a great deal of defensiveness in industry in the last few years because they have been under attack. I noticed that

more than 50% of his talk was about recognising the problem and discussing ways in which industry could contribute to solving it.

Amir Attaran: Harvard University

My study was referred to twice, which is a great surprise to me. Let me try to articulate some of the points of it so that it is properly understood. The leading finding that we published in JAMA last year is that there is a neglected half of the patents and access to medicines debate. We typically hear a great deal about how patents make markets. We hear distressingly very little about how markets make patents. Very often the rhetoric that is used in describing the access to medicine problem in relation to patents focuses on diseases that affect the poor and yet that is precisely where we find the extent of patenting is least. So the existence of patenting which theoretically is argued to underlie the problems of the poor is questionable as rare where those problems are at their severest, which suggests that the stronger correlate of the health problems is something other than patenting. I do not mean to say that patents are never an issue in access to medicines, certainly sometimes they are, but they tend to be so in the middle income countries rather than the poorest where, as I emphasise again, the health problems are concentrated. Therefore, in economic, health and patent terms Brazil is not Burkina Faso so South Africa is not Senegal and we tend to lose this distinction quite often as we discuss these problems. I would like to flag a point made by Francisco that Brazil, not being Burkina Faso, being a country with extensive patenting of medicines, has actually been able to use the compulsory licensing mechanisms, or at least threaten them if not invoke them. To some degree of satisfaction to me it suggests that the TRIPS Agreement, albeit with some flaws, is functioning somewhat well at least in the case of Brazil. What I would like to suggest is not simply to consider Intellectual Property Rights but international poverty wrongs. The problem of health overwhelmingly is one of poverty for the low-income countries where 2.3 billion people live. The WHO Commission on Macroeconomics and Health reported 2 months ago that a foreign assistance package of about \$27 billion a year is needed just for the low-income countries. We are today perhaps putting about \$6 billion in. This is an impasse of primary importance. The patent issue for the low-income people of the world is of secondary importance and we must retain that sense of priority in so far as our mission is to address the health needs of the poorest. Therefore I would respectfully submit to the Commission that as it prepares its report it must clearly differentiate....**end of tape** from the low income countries and secondly heighten what is a building international consensus that for the low-income countries it is actually an absence of wealth that is most impeding access to medicines and health at the moment.

Mary Moran: Medecins San Frontieres

The comment that patents are not the problem and that we are talking about diseases of the poor. In fact, I think what MSF is trying to say is that the patent research dynamic is central to the problem or rather the faith in the fact that patents stimulate research. Mr Mallet made a number of points, which I would like to discuss. One is that patents stimulate wonderful new cures and I think that is true.

However, that is only in a market context. Many of you here will be very familiar with the statistic that since 1975 we have had over 1,300 new drugs and of those only 11 have been for developing country diseases. Of those 11 nearly half have come from veterinary research into diseases that we share with some livestock and domestic pets. When MSF works in the field and treats these diseases with the off patent drugs that you mentioned we are using drugs which are dangerous, obsolete, ineffective because, in fact, the patent system doesn't stimulate research into better alternatives. The patent system is central to our inability to treat properly. A brief example, for trypanosomiasis or sleeping sickness there are 4 off patent drugs. One dates from 1917, one from 1939, one from 1949 and it kills more than one in twenty people that we give it to because it is an arsenic derivative and the fourth and final drug, the only modern drug, came inadvertently from research into a cancer cure. When it was found not to be terribly effective against cancer it was pulled from production for reasons, which I understand it, is a sensible business decision. We went back to using an arsenic derivative. It came back into production last year and the reason for that was that a market mechanism finally came into play. It was found to reduce the regrowth of facial hair and it was brought back onto the market as a cream and it sold in Manhattan pharmacies for about \$50 a tube. That is a market, as American women don't want unsightly facial hair. The fact is, it is not a sensible dynamic. It is not a reliable way to manage developing country diseases. As long as we keep saying patents aren't the problem, we have to say that we are not talking about the social contract between patents and research. That contract was meant to be increased global patent protection with health safeguards in return for global research. We had stronger global patent protections often without the health safeguards and in return we had research really into western diseases. So developing country price mark-ups on patenting goods are subsidising research into western diseases. And we will all agree that was not the intention and not how we wanted to operate. That said, I support patents, MSF supports their role in research, we agree that there are many causes of the problems and poverty is certainly central. It is a little tiring that whenever we want to talk about IPRs the industry starts to talk about development issues. Industry has very little influence over development unless they want to become major contributors of funds. So I think we should really stick with what is industries break and where they can have an influence and that is their approach to IP.

Joelle Tanguy: Global Alliance for TB Drug Development

I want to second some of Robert Mallett's points, but also argue against another one. I think we all agree that infrastructure and financing are key issues in the debate of access. I would add technology transfer probably. To actually make those points to argue that IPRs are less relevant to the access to technology debate seems to be a bit farfetched. Particularly when the arguments that are brought forth are, for example, studies on patents of drugs such as TB. I speak from an experience where at the global Alliance for TB Drug Development we are facing a situation of lack of drugs for TB for the last 30 years and trying to use the current system of IP to creatively and collaboratively with industry develop new drugs, yet I think that to use the TB example as an example of IP being irrelevant to the question of access is forgetting a few points which I would like to make. One is that substantial progress has been made since 1993 to access to TB treatment and the problem doesn't seem

to be only the infrastructure but, most importantly or prominently, the lack of new drugs that would reduce the length of treatment and address the resistances that have been built in and the absence of drugs in the last 30 years is due to the fact that the TB market is only a few \$100million and well beyond the blockbuster threshold expected today by current economic infrastructure when it comes to drug development. So the expectation is that in TB the return on investment would be too low and when we always have the discussion as to whether its IP or infrastructure or financing, I find myself very frustrated thinking that we can't on the one hand say innovation equals IP and consider that it would be a legitimate interest for all of us to consider how the IP system in the future should, therefore, be designed so that innovation in health serves all the population and enables the development of drugs that also serve the developing world. Today these new initiatives, public private partnerships not only in TB but in malaria and others, are trying to make creative use of the current system but wouldn't it make sense rather than creating adhoc mechanisms in the future to address neglected diseases to actually build into the system mechanisms that ensure that incentives are built into the infrastructure providing incentives to the players and investors to also address drugs for neglected diseases. That would be the recommendation to the Commission.

Robert Mallett

I appreciate both points that have been made. I don't necessarily disagree with them. Actually, I think we have made substantial progress here because I understood from a lot a reading I have been doing and Pfizer has been a well-worn target of one NGO that because of our stance about patents, patents were keeping people from getting their medicines. Well, we have made some progress today, because the suggestion that the IPR system as it now exists is not appreciably incentivised to bring new innovative drugs to developing countries around their diseases is one that we should be talking about. What are the steps we should be taking to incentivise companies to be able to do that? I agree with that and that would be a very helpful and worthwhile conversation. That is not, however, the conversation that has been taking place in the last 8 or 9 months so I actually believe that we are making substantial progress in talking about this issue. I agree entirely with what Joelle Tanguy and Mary Moran said and I think that we would be more than happy to engage in that conversation, if we can get the conversation focused there. That's not where it has been.

Eric Noehrenberg: International Federation of Pharmaceutical Manufacturers Association

Francisco's Cannabrava's presentation has made clear what this whole debate is about. It is not a debate about access to public health, not a question about access to healthcare but much more a question of industrial policy. You talked about Devine right to patent but there is also no Devine right to copy and indeed the experience of your own country should actually illustrate the fact that there are a lot of problems in local production. As you well know, it is extremely expensive. The Brazilian local copiers are subsidised to the tune of \$15million a year for treating 90,000 AIDS patients out of a population of 160 million people. Brazilian health officials have

already said quite clearly, this is not a model for other countries, it is not something that could be copied very well, unless you have as much resources as a quite rich country like Brazil. As a German from India said "Brazil is a rich country with a lot of poor people living in it". When talking about IPRs we should really make a clear distinction between the public health debate and access debate, which my colleague Robert Mallett said quite clearly on how we are actually working hard to make people have access to drugs. As to Industrial Policy, should people be allowed to copy things, should they be allowed to produce them without going through the trust procedures? For example, a very important one is that there must be prior negotiation with the rights holder before you can go ahead with compulsory license. As our experience has shown, not only in Pfizer but Merck. Other companies have all shown that if we are working with responsible partners who are committed to inviting healthcare for other people that we will find solutions. They could be donations, they could be some infrastructure projects and they could be reduced prices. We are open for that, but this has to be done first and trying to run around that by suddenly jumping to compulsory licensing, as a first option is contrary to TRIPS and contrary to good public sense. A last comment on this point is also again on the subject of industrial policy here, we are talking industrial policy benefiting certain net income countries. This is not going to benefit the least developed countries of the world. Who are the net copy manufacturers? They are in Brazil, in India, some are in China, but they are not in Africa. This is not helping African producers. When you are working in partnership with our industry you are getting the benefits of top quality products on a sustainable basis with follow-up. We believe in quality healthcare on a sustainable basis and we encourage governments and responsible NGOs to work together with us instead of working against us and focus on the real problems of public health.

Gopal Dabade: Buko Pharma-Kampagne, Germany

I am a medical doctor and I would like to share some of my experience of having worked with the poor and have seen in rural villages in South India that drugs are accessible for the poor. A simple anti-asthmatic medicine costs around ten rupees, which is a weeklong treatment and one day's earning. Drug prices are the lowest in India but this was not so earlier. According to the US Senate Special Committee's report in 1965 the drug prices were amongst the highest in the world as India depended heavily for its drug needs from imports and on multinationals. It was the Indian Patent Act of 1970 which brought in a change as it allowed only patenting of process and not for product. The reason for granting process patent in drugs and medicine was that they were considered essentials. Also, the patent trade was reduced to five years. We have looked into some of the drug prices and we have seen that the drugs are 1,000 to 4,000 percent cheaper than in USA. So that is the result of this patent act and not only that. The new drugs that were introduced into the market were much quicker. Before 1970, before the patent act was introduced, penicillin was introduced in foreign countries in 1941. In India it was introduced in 1963, which took 22 years. After the patent act was introduced in 1970 a simple drug, rifampicin which was introduced globally in 1974 was introduced in India in 1978 which took just 4 years. One more example, mebendazole, a common medicine used for treatment of worms was introduced globally in 1977 and in India in 1978, just one year after the global introduction. This quick introduction into the market

was due to the Indian Patent Act of 1970. I would request the Commission to look at how developing countries can make use of parallel imports and compulsory licensing. We welcome the decision taken at Doha, the right to protect public health and, in particular, to promote access to medicines for all. We are following the developing drug donation in African countries and if they are donor driven and they tend to unnecessarily alter and change health infrastructures and as one of the participants presented, it has hardly touched a very small percentage of the people who are really affected. As it is meant only for mother to child transmission and not for the triple dose treatment.

Francisco Cannabrava

Regarding Amir Attaran's comments, of course Brazil is not at the same level as Bukino Faso. I think we all recognise the distinction of industrialisation of economic growth among developing countries. What we do have in common, however, is weakness when it comes to making sure that the interpretation of the provisions of the TRIPS Agreement is going to be taken in our favour. The TRIPS Agreement as you know is extremely ambiguous in many relevant passages. I think it is important to make sure when those ambiguities are considered they are not misused and countries do not take a narrow approach and more important than countries The Dispute Settlement Body do not take the existing provisions of the TRIPS Agreement under a narrow approach that is going out naturally to represent limited access to drugs, so I believe the real danger of the TRIPS Agreement still exists. The Declaration on TRIPS and Public Health was extremely useful in that respect. As I said, the battle is not over. Try and issue a compulsory license yourself in a developing country and you will see what is going to be the political pressure, the reaction and the amount of narrow interpretations that you are going to hear when you try to make the TRIPS Agreement function in a way that is supportive of public health. The ambiguities are still there, the Declaration was helpful but we will see from now on what way the TRIPS Agreement is going to function. I cannot agree with you that the TRIPS Agreement is functioning well. I think that we had satisfactory results in that respect, but unfortunately I cannot say that the TRIPS Agreement is functioning well, or if it is working well for whom. Regarding the point that the absence of health is impeding access to medicines, I cannot disagree. I think it is curious that in the debate on IP and access to health, I don't remember hearing the side of those that advocate better access to medicines in favour of more flexible IP rules. I don't remember hearing anyone saying that the only problem of access to medicines is patents. Take the most radical NGO, the most radical country, I do not recollect anyone making that point. I find it very odd to hear from the other side that there are so many other problems that, therefore, we should not discuss the issue of patents as a problem. Frankly, I do not understand why some people feel so uncomfortable when the issue of patents is actually discussed when we discuss objectively how patent rules can now, and in the future, affect access to medications. Let me emphasise that, certainly from the perspective of the Brazilian Government and I am sure that quite a number of other developing countries are of the same view, we do not run away from any possible practical solution. Brazil is very much engaged in the discussions on the global front. I am not a health expert myself, but I do follow that discussion. I know that my Government is very much engaged in that discussion, not as a potential beneficiary but as a potential donor of

technology. The issue of differential prices with benefit from differential prices, we are not against differential prices, we could not be against that concept if it represents better access to pharmaceuticals. We are absolutely in favour of public private partnerships. I don't think it falls in the usual category of PPPs but very recently the Brazilian Government and the NGO, Medecins Sans Frontieres, has established an agreement to provide drugs to South Africa on a non-commercial basis. I cannot say that we are running away from every possible discussion and we will definitely not refrain from addressing the impact that patents have on access to medications. Regarding Dr Noehrenberg's point, I cannot understand the problem with advocating transfer of technology. That is the objective of the TRIPS Agreement. I don't understand your objection to that point. If we should take away that element from the TRIPS Agreement, I do not see what the purpose of the TRIPS Agreement would be for developing countries. It is better not to have the Agreement if we do not have that element which is the minimal we can expect for developing countries. Regarding the preservation of the right to copy in Brazil, as you know, what we have in terms of the existing, the strongest pharmaceutical industry established in Brazil, is exactly the international pharmaceutical industry. What we have as domestic, as indigenous, pharmaceutical industry is very small. We are not India. India does have an extremely wealthy and rich genetics pharmaceutical company. I wish we could have the same strength in terms of being prepared to produce generics but the reality is that we are not in the same position. What we have has been absorbed by the multinational industry so that's the reality and I find it contradictory to hear from a representative of Pharma that Brazil is applying an industrial policy in Brazil. It must be only for the benefit of the international pharmaceutical company and we do provide even tax incentives for the pharmaceutical company so what are we complaining about.

Jeffrey Kemprecos: Merck and Co. Inc.

First of all, Francisco is a very skilled and well-briefed negotiator and wish he could work for the Americans. One of the ways you would solve the ambiguities in the TRIPS Agreement would be to have, for instance, dispute settlement and, of course, Brazil and other countries have tried to thwart dispute settlements or place an indefinite moratoria on them. That inhibits the ability for the WTO member states to work out how you could solve the ambiguities. These extra agreement declarations we get seem to be the preferred route. I think Brazil has benefited enormously from its patent law and the change in the overall commercial environment there since 1996. I don't have the precise figures, but its to the tune of hundreds of millions of dollars in new investment from the multinationals and that clearly represents technology transfer. So I would ask Francisco, well how much is enough for Brazil. You have mentioned technology transfer several times. Brazil in the mid 90s anyway was doing many things to not only encourage our investment but serious investment internally from a budding biotech sector. Which brings me to my last point. It will be interesting to see Francisco in Geneva one day when Mexico is issuing a compulsory license for one of the biotech products coming out of Sao Paulo and I think these interests shift back and forth and none of them appears to be set in concrete, not that I want that to happen having lived through it in Brazil. It is not the most favourable investment or commercial environment when one negotiates with what is, in fact, a gun to the head. The New Yorker had an article in mid-December on India and I invite people to read this because it really strips away much

of the sloganeering and gets to the complexities of dealing with health in very poor countries. The figures in India are simply appalling. I ask the Commission to please look at India. India is held up to us over and over again as the patent free paradise. Consider these figures, estimated HIV positive in India today, 4 million people, estimated AIDS case, 500,000. These are the people who, if they don't get treatment very soon, are going to die. Estimated patients on highly antiretroviral therapy, the figures we have from UNAIDS are less than 2000, that's less than 1%. Actually, to be conservative, I put it at 3,000. Maybe UNAIDS has undercounted, but the point here is that less than 1% of people in India who need treatment are getting treatment. The patents on antiretroviral drugs in India, according to Dr Gopal Dabade, are zero. None of them are patented. My final point, we have been reading lately about access to essential drugs. I would encourage people to take a very close look at access to essential drugs, particularly in Africa. Of the 308 essential drugs we found three that had patents anywhere in Africa. It is nice that we have the luxury here in London to discuss this tiny slither of drugs that are under patent but what about this great sea of grain. I think that is the task and I invite the Commission to take a look at the essential drugs situation worldwide and in Africa.

Gichinga Ndirangu: ActionAid

I think to a large extent I agree with many of the issues that Robert raised that we have to look beyond patents and look at the other wider questions that effect access to drugs. As we speak about access to essential drugs, particularly on the so-called diseases of the poor, we see that there hasn't been much emphasis on the question of developing, for example, a vaccine, that much of the research and development is still directed more towards new lines of treatments, new drugs, yet a vaccine could probably be one of the solutions that could lockup the problems we are talking about and I say this because if one was to look at the whole question about the fact that in a country like Kenya, for example, they have development statistics saying that 50% of the population is living on less than one dollar a day. Even if you have differential pricing on these drugs, the truth is that the drugs are still lying on the shelves and nobody can afford to buy them. The disappointing thing which we face is that we do not find the pharmaceutical industry giving equal emphasis, for example, to how do we resolve this problem when we talk about extremely poor people who are suffering from life threatening diseases whose only hope might probably be if we are able to put emphasis on the development of a vaccine.

Yusuf Hamied: CIPLA, Mumbai

I think the representatives from the multinationals are a bit harsh on India. We want compulsory licensing in India. We have nothing against patents we only want compulsory licensing, similar to what Canada had before 1992. We want a permanent compulsory licensing system, an automatic licensing system. We do not have to go to the originator for permission and we will pay a royalty of, say, 4% on our net sales to the originator. We want this system of parallel imports, whichever country has cheaper products we do not mind importing. We want the life of patents on essential medicines, particularly for the Third World, to be restricted to ten years. This is the Product Patent. We want research on a non-commercial basis to be

allowed as in America under the Bolar Provision. We want that there should be no ever greening of patents. For example, the AZT invented in 1964 as a single ingredient drug is patented to 2005 and combinations of AZT are patented in the Western World until 2017. I think that is totally unjust and there should be some form of patenting whereby once the basic patent is off, all formulations except in the drugs area, should be off patent. Patents Law is a national law. Every country has to decide for themselves their own destiny and, therefore, what India needed and did in 1970 was that there are two basic needs, food and health, and on these two issues India did not compromise and I only hope in the future, again on these two vital issues, India does not compromise. India today has .4% of the world trade, which is negligible. I have also requested the Indian Government to decide whether it is worth being in the WTO. Let us create a Third World Trade Organisation to compete with the WTO. Lastly, there is a golden rule, the countries that have the gold make the rules and I think this applies also to multinational companies that they try to make the rules.

Trevor Jones: ABPI

I would like to ask Yusuf Hamied whether the profits made in India and the research carried out in that nation could be turned to the kind of diseases which are prevalent both in India and the developing world, because it is not evident to me that that is actually what is happening with the profits made in India right now.

I want to ask the Commission to consider very carefully the need for strong patents in the areas of the developing world diseases. The medicines from Malaria Venture like the Global Alliance for TB is a misused word, public private partnership, it is an endeavour we set up with funding from agencies like Rockefeller, The World Bank, Bill Gates, The British Government, The Netherland Government, Swiss Development Corporation, but regrettably, no other governments to actually bring realistic practical solutions in an affordable way with new medicines for malaria. Unless we protect those with patents, these ideas incidentally in a very balanced portfolio from discovery right the way through to market are coming from academia and from the big multinational drug industries. It has been worked out with them into practical solutions. Unless those are patented, we are going to find a diversion of products when we get to the end point or worse, perhaps, multinational companies ripping it out for the travellers market and the developed world and we wont get the income back. I would ask the Commission to ensure that in these areas as in all areas the TRIPS and the strength of IP be maintained. Then we shall be command of a method of getting these medicines properly to the people who need them at an affordable position. Isn't this what its about. I heard a speaker, the man from Brazil, talk about the other side. Why are we all throwing bricks at one another? Why don't we pick those up and build bridges and sit together and work this through. Especially in the context of 31f where I do believe that a sensible dialogue between the originator and the country of need can result in effective solutions.

Miranda Lewis: VSO (NGO)

It is somewhat disingenuous to talk about essential drugs lists in the context of pricing as many of the drugs we are talking about are explicitly excluded from essential drugs lists precisely because of their high prices. Also, VSO is aware of the problems of poverty and health infrastructure but nonetheless our health workers and colleagues on the ground say that high prices of patented drugs remain one of the main barriers to people actually accessing and using those drugs. Mr Musungu highlighted a couple of the problems both with donations and tiered pricing schemes that are floating around at the moment and I think it is important to be very clear on the distinction between a donation for a disease where the goal is elimination, such as trachoma, and a donation when the disease needs to be treated for the rest of someone's life. One of the solutions that has been talked about and eluded to here is the issue of tiered pricing. It is very important when we are looking at that and looking at how such a scheme would work to remember that a unilateral price offer from a particular drug company to a particular country does not constitute a systematic means of making prices sustainable and equitable for the group of developing countries. We need to remember that it is vital that the flexibilities in TRIPS are used to make sure that generic competition is able to bring down the prices as we have seen already beginning to happen, offers such as the Accelerating Access Initiative, as soon as companies such as CIPLA made their offers.

German Velasquez: WHO

A comment and a suggestion for the Commission. There is a growing argument made by the industry of the number of patented drugs on the Essential Drugs List. I think that Merck are losing time and money because we made this study three years ago and we recognise that 93% of the drugs are out of patent. That is true. But the question is not how many drugs on the Essential Drugs List are on patent or not, the question is what is the value of these very few drugs, because we know in the WHO that less than 10 drugs sometimes in a country can represent 50% of the value of the total consumption of the country and that totally changes the situation. We are not talking about now, we are talking about what is going to happen in 5 or 10 years from now. With today's trends, many drugs on the Essential Drugs List are going to be patented drugs. Finally, on the question of no patents in Africa, I think the approach of the studies commanded by the industry is not the correct one, because we now very well that the African countries are importing drugs. The patent for them is the patent in the sort of countries that are creating a problem for access to drugs.

Sisule Musungu

Apart from talking about importation which many people would want to see as importation from India, if you look at the coverage of patents, for example, in Africa, you will see that certain markets are blocked and those would be the markets with potential. As we talk about infrastructure, I think it is important to think that if there are fewer infrastructures then we need treatments that can be easily managed. In terms of ease, combivir would be a good example. It is easier to manage because it is two in one and therefore more useful. If we are trying to promote an infrastructure

the easier to use options would be the ones that we look at first, but this is, for example, one of the treatments that is easier to use but with most coverage. Again, I will go back to the point I made when I began. We were talking about how patents help poor countries. As people have pointed out there is a problem in research for neglected diseases. What contribution can IPRs make to that particular problem? It has been pointed out that many of these countries already had fairly strong patent systems, some of them drawing from the UK, basically some of them were applying the UK Patent Law and has these systems, but there is still a problem in research for the diseases that affect those people. I think it is important to look at that in terms of talking about incentives and how, eventually, having much fewer treatments, how the IPR systems would assist in getting those to people. Regarding technical assistance, probably it might be useful for the Commission to consider the laws in the least developed countries that have been developed with technical assistance and consider how those laws have been tailored to meet the needs of developing countries. Have those laws included the flexibilities that TRIPS allow these countries, specifically for laws that have been developed, for example, with the assistance of WIPO or any other technical assistance. USAID has been giving some technical assistance to develop laws for developing countries. It would be interesting to find out**tape change**... I think, finally, a point that was mentioned about dispute settlement being the method to determine what the law is about. That is fine for people who can afford it. If you are asking Mali or any other country because it thinks there was a problem with public health and instead of trying to go through the TRIPS Council and solving the problem at that level, go to a dispute settlement with the US. That process is too expensive for them. No developing country with all the bilateral pressure is going to go to dispute settlement. I don't think it is necessary to encourage countries to go to dispute settlement for issues that are fairly clear. Prices have come down dramatically over the last year for ARVs. There is another problem that probably the Commission would like to think about if it has any relationship with IPRs. There has been a significant level of shortages for this treatment after the prices came down, either because of poor planning logistically or for other reasons. I understand that one of the reasons that prices have come down is repackaging. In some countries there has been a shortage of crucial treatment in the combination for two months. If we are dealing with resistance and problems like that we need to look at these problems in order to deal with them.

Robert Mallett

TRIPS was designed to establish and harmonise IP rules in an emerging global economy, to create a sort of international rules of road so that everybody understood what the rules were. That there would be more transparency and with the idea that also, if we all understood the same set of rules there may, in fact, be more investment in emerging economies. To that extent, it has only been partially successful, but to the extent that the IP system upon which we all depend to bring us these miraculous therapies, the system we know today seems to be working. Now TRIPS is as much a political document as it is a legal one. Much of the work at Doha and the work that will continue is to make that political document real to people so that they could believe that they have a stake in this system. I would urge the Commission and all of us who are working very hard, I think, to get medicines to people who need them, I hope that we will do whatever it is we are going to do

around TRIPS in a way that does not undermine our ability to get these medicines to the people who need them and continue to give us the ability to bring new therapies to people, because that is the only way we will ever solve any of these problems. So my emphasis on infrastructure and financing is real. If we had used the amount of energy that we have expended beating the brains out of sometimes politically tone-deaf pharmaceutical companies, if we had spent that level of energy concentrating on African governments to invest in healthcare, on the US and other developed countries to make more substantial contributions to the global fund, to reduce debt, I wonder where we would be today. You certainly have made great progress in getting the attention of multinational pharmaceutical companies. Declare victory, because in that way you did a very good service for people who are poor, because we are fully engaged in trying to figure out how to solve some of these problems. I think you should join us in figuring out ways to get medicines to people. Many different strategies work. We also have to work on our own Government and governments in developed countries to get their attention around this problem. If we could come together to do that, I think we would be a hell of a lot better off.

Francisco Cannabrava

I would like to refer briefly to the last comment. The truth is there are pretty much two sides, but I don't mean to say that there should be an antagonistic or that discussions should freeze on two sides. As a matter of fact, the exercise we are engaged in here exactly demonstrates that we are looking to sustainable and effective solutions, both within the domain of IP rules and outside. The focus today happens to be on the effect that the IP system may have on public health and what we believe is that it should definitely operate in favour of those objectives. I agree with Mr Mallett on the fact that TRIPS is both a political and legal document. I think that this is very important to bear in mind because we should not take the TRIPS Agreement from a narrow perspective of what is the least of flexibilities that we can achieve from that. The TRIPS Agreement contains very important provisions that take into account the need of developing countries to promote social and economic welfare. Under this context we should try to look for ways of implementing TRIPS in a way that is simply going to both preserve patent rights, and try to avoid abuses of those rights. I don't think that anyone who is interested in preserving patent rights should defend a point of view that they should be absolute or sacrosanct. It is just a matter of preserving the legitimate goals of countries of pursuing public health policies. My final point is to stress the important element of countries with insufficient or no manufacturing capacity which I think is one important element to be taken into consideration in your recommendations. I would like to praise the Commission for organising this conference.