

**Access to Treatment:  
People Before Trade  
XVI International AIDS Conference  
August 16, 2006**

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[START RECORDING]

**FEMALE SPEAKER 2:** [Inaudible] precedes people. I'm going to introduce our speakers. The first one, Alessandra, who is the director president of [inaudible] an Inter-relational [inaudible] Group in that it [inaudible]. [Inaudible] counsel issues like in America. Alessandra, if you can please take the stage. Each of our presenters, please remember, you will have a maximum of 11 minutes. Because we want to allow for question time.

**ALESSANDRA NILO:** Thank you. Well, thank you to the organizers of this conference, inviting us to speak on these issues, especially at the time where we saw in the last month the failure of negotiations in the World Trade Organization [inaudible] after that can start thinking that another way to discuss commerce in [inaudible] possible and that people must be before trades.

So firstly, I would like to apologize because I prepared my presentation in Spanish since I thought that we would have translation here from Spanish to English speaker and just now, they told me that it wasn't possible to have this kind of service. So my presentation will be Spanish but I'm trying to translate it to English to make possible all of you to understand what we are trying say here.

The first thing is trying to bring to you a context where you were discussing this issue of access to treatment

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in Brazil and I was required to talk here about our [inaudible]. We are taking the [inaudible] against [inaudible] laboratories in the case of [inaudible]. But I think that's important that you understand that how the health system in Brazil is working regarding access to help and treatment in general.

So we have here 988, our Constitution that guarantees right to health as a right that must be an obligation of states to provide to everybody. So in 1993, we started [inaudible] a local [inaudible] out of [Inaudible] and as for that DBI and in 1995 we had [inaudible] and in 1996 [inaudible] until 2005 has been [inaudible], for example, within the government to sign the agreement.

And in 1996, we had this property industrial law that [inaudible] today we can affirm that make a huge problems to at least almost 2,000 companies and laboratories and Brazil that was [inaudible] production of some kind of medicines. Especially that could be possible to be producing HIV medicines. It was a huge impact on our system.

As you see here we have also [inaudible] which is a [inaudible] that all the guys they oblige this stage to provide free medicines to everybody to who needs that, free medicines to HIV and AIDS, so [inaudible] we have two laws, different laws, that at the same time have this good

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perspective of having three retro antiviral for every body who needs.

Now [inaudible] AIDS and retroviral drugs but is providing almost 18 [inaudible] providing drugs for a 175,000 people in Brazil who are needing these drugs. So we have all these numbers of people receiving treatment in Brazil now, nowadays.

In 2001, we started to reach the discussion of [inaudible] laboratories that they don't lower the price. We will issue a compulsory license. It's got to be with [inaudible] in 2001, but we just got a reduction of price. In 2003, the Brazilian government set up the baseline for how could [inaudible] and Brazil compulsory license? In 2005, the [inaudible] and health minister started some discussion about how could it be possible to have a license to implement to relieve the compulsory license for some medicines.

We have a huge crisis in that year. The end of the year and the beginning of 2005 we had a lack of medicines and the government was saying that it was infrastructure problems. It was not specifically related to lack of money, but a lack of infrastructure to deliver the medicines.

In 2005 the Brazilian government set up a dead line to [inaudible] Abbott and Merck, regarding [Inaudible] a voluntary license for these treatments and I am referring here in my [inaudible]. But the laboratories just didn't

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listen to the government and they just care about our treatments again.

Here in this slide we can see the difference, the impact of the starting giving second line drugs to people in Brazil. So we have in 2004 almost 600, more than 600,000, millions of [inaudible] for medicines. And in 2005 when we had some more expensive medicines this resource was to almost one billion per year. So the second line of medicines was a huge impact in our budget for giving pre-medicines to Brazilian people.

Now we have three [inaudible] provider drugs that according to Brazilian government almost 8-percent of our budget we had to provide medicines to the people in Brazil. And we had now [inaudible] taking almost 30-percent, 25- to 27-percent of our budget for giving free medicines in Brazil.

We had a lot of progress and we went to the street many times asking government to issue the compulsory license. We have also strong support for international communities so we had process London. We had, there in the United States, in New York and San Francisco but it doesn't matter. We didn't achieve our goal.

So our Minister [inaudible] said that time was became known as tiger without teeth because each time he was an international meeting he was [Inaudible] to you the compulsory license but we never did, unfortunately. Also in

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June the Brazilian government declared that compulsory license [inaudible] was a matter of national interest.

The Brazilian counselor of health also issue a resolution asking for a compulsory license for [inaudible], but in and this is the problem, despite all effort we had everything organized. We had opportunity. We had the right people in the right place. But in October 2005, the Brazilian government signed a horrible and a bad amendment with Abbott to buy Kaletra until 2011.

It was a shame for Brazil. It was a shame to the Brazilian government and now we have to buy Kaletra for 63 cents off the dollar instead to be producing Kalatra for one cent off a dollar. Also the government is about [inaudible]. And there is nothing about [inaudible] of technology too.

We had a strong reaction, of course. And we need to know to say that we have a group in Brazil named Rebrif [misspelled?], which is very well organized around this issue. Rebrif is coordinated by Abehim [misspelled?] in Brazil.

And then [inaudible] that [inaudible] group, we decided that it was time to do lawsuit against the government because the government was not respecting our right to [inaudible] and was putting the Brazilian national problem to provide free medicines to Brazilian at great risk.

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We are under a great risk now and to keep providing universal access to everybody who needs would be a big challenge in the next years for Brazil. So this is the kind of, this is a frank situation we are facing there. Because at some time we are known as to have one of the most well organized National AIDS problem, we had also decision-makers in government that are not agreeing that right to have is, must be guaranteed.

So it's a kind of contradiction and for the next, for 2007, we will have an increase of almost 50- or 60-percent of people in second line it would be impossible to treat. So the lessons we learned was there is no risk factor to the international agreements or international resolutions.

So now I just wrote down some of the main resolutions in governments we had in the last time and my question here is we need more resolutions. We need more agreements, since World Trade Organization agreed, United Nations agreed, World Health Organization agreed, how to write more important than commerce. But this is not happening at the national level.

Also we learned that we can do what they say but we can't do what they do because many countries, Canada, United States, Australia, [inaudible], many of them are using compulsory license for many years when they need to use it. But for us in this non-developed or developed country this is not possible to do.

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What is going on here? We are talking about rights or not. And rights, human rights are for everybody or just for some parts of the population in the world. I think this is a question we need discuss here.

[APPLAUSE]

Also what we are seeing is that about revolutions and process in agreement it doesn't matter to because when the, these governments are not satisfied with these agreements they just go into the bilateral agreements or free trade agreements and they do what they want to do there. So, thank you, so also all these choices are impeding us in developing countries to strength our capacity of production and to strength to our capacity to really guarantee human rights to everybody who needs and deserves human rights.

So why just these countries can issue their lists of compulsory license, this is my question for this discussion. Also I think it's important to reflect that [inaudible] health care is not for commoners. And I think that we have three things that are important to make sure that we will win HIV and AIDS.

One is to have the participation of [inaudible] society in all classes. Second is to guarantee all possibilities [inaudible] implement the human rights to everybody. And third is the political view of our governments to do that. In Brazil, it is a case where we

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have the [inaudible] participation. We have really beautiful laws to guarantee human rights but we do not have the [inaudible] of our politicians and I think this is my message for this conference. Thank you.

[APPLAUSE]

**FEMALE SPEAKER:** Thank you, Alessandra. Now next in our program is Anand Grover from India. Anand is a practicing lawyer in India, and he's also working with the project as a project director for the Lawyers Collective and HIV/AIDS in India.

**ANAND GROVER:** Okay, this is in relation to what has happened in India. Now until 1970 in India it was a law which is very similar to laws in other countries. But in 1970 when Mrs. Gandhi was in power, she realized that the right to health is very important.

And what she did was introduced a new law where she actually deleted the protection for whatever [inaudible]. Only [Inaudible] were protected and because [inaudible] protected [Inaudible] you had new genetic users. It enabled competition and as it [inaudible] prices came down. I also did [inaudible] of this drug manufacturer in India started coming down.

Now, in that law which existed even right prior to the law that came in, 2005 there were provisions of abuse [inaudible] compulsory licensing and consolidating of

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availability and access. Now India [inaudible] like a lot of other countries [inaudible]. The [inaudible] regime requires if you're [inaudible] regime, it's mandatory that you are to comply with it. If you don't comply sanctions can be imposed like for example [inaudible] Declarations of Conventions of Human Rights. If you don't comply with this Declarations of Conventions, then all you'll have is some abuse from the International Community, but more sanctions can be imposed.

Now the [inaudible], the regime, the [inaudible], require certain things to be done. One was patients' ability minimum standard was established. Within the minimum standards countries would have flexibilities. The protection was to be for both products and [inaudible]. And the minimum [inaudible] was to be for 20 years. Now between 1995 and 2005, because different countries were [inaudible] compatible law by different dates. So India was supposed to comply with it by 2005. At least [inaudible] by 2016.

And they also gave the minimum conditions for compulsory licensing. Now the [Inaudible]. Compliant Law applies to drugs which come into the world when it was signed. In the [inaudible] which in [inaudible] 1995 and one in 2005, there is supposed to be seven provisions and one of the provisions is important for my talk is what is [Inaudible] exclusive marketing rights? Now, if a company had an agent in another [inaudible] country and marketing

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approval, it could come to [inaudible] also that [inaudible] country and get exclusive marketing rights. I'll explain that again later.

Now in March 2005, India enacted a [inaudible] law. Actually [Inaudible] in January 2005 but the actions [Inaudible] effective March 2005. It defined invention which is in compliance with [inaudible]. It has to be for the new products and the process which it was [inaudible] step and it has to be new and it has to be capable of industrial application.

What is important for us in our debates is what is Section 3D? As I explained to you earlier under the TRIPS agreement each country could have flexibility in defining what would be protected. India had to protect product [inaudible]. But it had the flexibility to do it in the [inaudible] countries. So what India did was, it said, we have a project protect absolutely new products but not new forms or new uses, except if they are significantly different [inaudible]. So as the Section 3D reads, The [inaudible] or the discovery [inaudible]. [Inaudible] efficacy of that substance. But this is not an invention. But the [inaudible] is actually [inaudible]. For the purposes of this [inaudible] et cetera, et cetera, et cetera and [inaudible] and known substances shall be considered to be

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the same substance. So this is all [inaudible] but it's a new form but it is the same substance [inaudible] mentioned.

This is very, very important because in the United States any new form, just like [inaudible] formula is patentable. And the difference has to be in property regarding to efficacy. And that this is [inaudible] significant. Similarly we [inaudible] are not [inaudible].

Now under the [inaudible] that exists now, there is a big dispute [inaudible] laws and [inaudible] be able to give concessions from the government. One of them was 3D. The other was to preserve what is like pre-ground opposition. Before agent is granted to the patent applicants any person can actually make an application to resist that.

And that enables an opposition. So before the patent is granted it's in its pre-grant position. After the patent is granted its [inaudible] position. Then there are other ways of checking availability and affordability. They are voluntary licensing, revocation], compulsory licensing, which Alessandra talked about, non-commercial publication which [Inaudible] will talk about.

And in India we have another system all together used to control bases under what [inaudible], drug price control, which applies to drugs which have a [inaudible]. But it doesn't really apply to governments to impose the drugs. Now

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the government is thinking of linking price control to Gandhi [inaudible]. That's a little thing [inaudible] bridge.

Now oppositions, is what I am going to talk about in the next few minutes. They are pre-grant under section 35-1 and it can be opposed by any person. And 25-2, which is post grant, the grounds are identical and I'll now go to some examples.

Now one of the cases which are going to court is the case of a drug which is on this [inaudible], which is an anti-cancer drug. It treats chronic Mylar leukemia. In December 2003, [inaudible] was granted exclusive marketing rights because it had got a patent [inaudible] and marketing approval in Australia.

So they came with that and proving [inaudible] under the TRIPS agreement you have to give a [inaudible] exclusive marketing rights. They got that and they fired [inaudible] against genetic manufacturers.

There are seven genetic manufacturers manufacturing the same drug. One of the [inaudible] difference will lock its price [inaudible]. [Inaudible] \$2,700 for the drug And genetic companies are giving that drug up to \$100 per month. And our clients, which is the Cancer Patient AIDS Association they were actually subsidizing it and giving it to the patients for \$25. So they are subsidizing to the extent of \$175.

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So when the Patent Act came into force in March 2005, they actually made the applications of patents. That's what you are required to do and we filed an opposition. In the application they said that our, this particular compound [inaudible] it is a [Inaudible] and they contended that a particular [Inaudible] was totally invented. It was a new product. It was significantly different in terms of efficacy and therefore they should be granted the patent.

They said it had already been granted in 35 countries and therefore India should also grant it. Now the Cancer Patient Association, the Cancer Patient AIDS Association, they filed an opposition. They said that it's not a new drug. It's [inaudible] form of a new drug. It's not, it's an obvious drug.

It's just a small improvement of a known substance and it is [inaudible] properties. And whether other countries grant patents or not is not relevant for Indian patent law because the Indian patent law has specific provisions. They don't allow, -there are certain things to be patented.

Now, in January 2006, the Patent Office, this is the first case in to which we decided whether a patent [inaudible]. They actually rejected the patent. And [inaudible] never expected that this would happen. And for a long time [inaudible] and now after that eight months they

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have now filed, just before I came from India, they filed a judicial review application. Two applications, one is to challenge, the other patent controller.

And secondly they challenged the validity, the constitutional validity of Section 3D which I talked about earlier. [Inaudible] Now, I don't know how they will succeed in that but that method is coming up in the [inaudible] courts on 23 of March. Now apart from, and believe me I could [inaudible] because it has to go through the whole process.

And [inaudible] is going to give [inaudible] to the Supreme Court so it's going to [inaudible]. And some of the groups of [inaudible] that actually meeting because on the 23 of this month there's going to be some protest.

The other oppositions that have been filed are of [inaudible], [inaudible], and [inaudible]. Most of these have been filed by the [inaudible] people. But we are also filing oppositions on behalf of our other health groups.

And those [inaudible] real interested. It is a group on Internet, which is for information about these issues. So you can look. What are the objections? Same thing, the invention is not new. It's obvious it's just a new use. It's not patentable under India law under Section 3D. If it's a combination of certain [inaudible], again it is not a patentable. And if it's a mixture it's a [inaudible] mixture

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and doesn't actually enhance efficacy at all, And some of the [inaudible] do not disclose that patent applications [inaudible] in other countries which [Inaudible]. So this is the position.

Now there's two other things that I would need to talk about. As it is now, why is this important, because India supplies 50-percent of the demand in the developing countries. So what happened in India and we got to these first line and second line and of course [Inaudible] will impact not only India but the whole of the developing world.

Secondly, unfortunately and shamelessly, India, which is the largest supplier of retro antiviral drugs has the cheapest prices. Indian positive people estimated to be 5.2 million out of which about 500,000 require the [inaudible]. You won't believe only 20,000 are getting it free, only 209,000. So Indian [inaudible] and this is [inaudible]. Thank you very much.

**FEMALE SPEAKER:** Thank you. Our next speaker is Sangeeta Shashikant from Malaysia. Sangeeta is the researcher of [inaudible].

**SANGEETA SHASHIKANT:** Good morning. What I intend to do in the time allocated to me is to talk about the Malaysian experience and how Malaysia has made use of the [inaudible] to increase access to more affordable ARVs and how the use of [inaudible] are now being undermined by the current

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negotiations that are taking place between Malaysia and the United States.

So in 2003 Malaysia was the first Asian country following the [inaudible] Declaration on [inaudible] and Public Health to issue a [Inaudible] order to import genetic versions of patented ARVs from India.

And for those who are not familiar with what [inaudible] is, it is basically a [inaudible] which allows a license which is issued by the government to make use of a patented product for it's use, for public non-commercial use without the need for prior negotiations or consent of the patent holder.

Now this was an initiative that was begun by the Ministry of Health because they had tried to negotiate with the patent holder to reduce the prices of ARVs but they are not very successful because the reductions that they received was still not sufficient and it was not enough for the budget they had allocated to procure ARVs.

So in November 2002, the Ministry of Health submitted a paper to the Cabinet to import ARVs from India and Cabinet approved it using Section 84, the Malaysian Patent Act, which allows for the use, allows for government use.

Now as you see the beginning section of the slide, this is the drugs that are imported under the government use

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authorization [misspelled?] and there are two patent holders that were involved [inaudible], BMS and GSK.

And below that is the conditions of the government use order and the important condition was that imported drugs were for the supply of the government hospitals and the government use was for two years.

Now as a result of the government use authorization the average cost of treatment per person per year dropped from \$315 U.S. dollars to \$58 U.S. dollars. And this is an 81-percent reduction in costs and this increased the number of patients that could be treated from 1,500 to 4,000 people.

If you look at the first box you will see that it dropped from 2001 the patented price was \$261 U.S. dollars and in 2004 the generic price was \$45 U.S. dollars. This is under the government use. And the second one is \$352 U.S. dollars which has dropped to \$115 U.S. dollars.

What is interesting is that as a result of the government use authorization [Inaudible], the patent holders themselves also dropped the prices of their own medicines. [Inaudible] they dropped about 50-percent from 2001. It was about \$63 U.S. dollars. In 2004, it came down to \$32 U.S. dollars.

It came down to there is \$2 U.S. dollars. There was about a 59-percent drop in price. There [inaudible] had an

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82-percent drop. GSC also dropped its prices. Community dropped by 80-percent, [Inaudible], 67-percent.

Now for the government, one of the requirements was that they had to pay remuneration to the patent holder. And this was a requirement of the [inaudible] agreement. And they are [inaudible] of 4-percent of the value of [inaudible] actually delivered. And according to the Ministry of Health [inaudible] the patent holder has shown more interest and this is information as of February 2006.

They're showing more interest in getting, collecting the remuneration and some of the reasons they give was because they feel that the patent holder might feel that it will set a precedent for future government use authorizations in the country. It could be very bad publicity for the patent holder. They accepted it. It is a sign of acceptance of their right to issue a Government Use Authorization.

And this is information that we got from the Ministry of Health. The Government Use Authorization ended in November 2005 and the Ministry of Health considered two options. The first was to negotiate prices of patented products to an acceptable level.

The second was to apply also for a renewal of the authorizations. But it seems that they have opted to negotiate the prices because they feel that they had a gone through the Government Use Authorization and that was an

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advantage and they could use that to negotiate prices of patented products, because as you saw as a result of the Government Use Authorization the prices of the patented products [inaudible] dropped drastically.

Now what are some of the challenges? One of the major challenges was the opposition from the patent holders. After the Cabinet's decision to issue authorizations, GFC offered to drop the price of [inaudible] by 57-percent.

There were complaints against the Malaysian government that were launched and meetings were held between legal representatives that questioned whether Malaysia was doing was actually legal under the [inaudible] agreement, and their suggestions that this would actually affect the investment decisions in Malaysia.

Now this kind of raised a lot of concerns with other Ministries. For example, the Ministry of Domestic and Trade and they have answered the question the Ministry of Health, to say, Look do not go ahead with issuing the Government Use Authorization. But the Ministry of Health should firm the Cabinet, reaffirm the decision and a lot of the strength over in Malaysia issued the Government Use Authorizations [inaudible] public health.

We also understand that a lawsuit has been filed in Malaysia by one of the patent holders, although this has not been activated. As you can see, Malaysia is just one of the

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countries that has accumulated use of the Government Use, has made use of the [inaudible] flexibilities. There are also other countries such as Indonesia, Zimbabwe, that have also made use of the [inaudible]. For example, in Indonesia, a presidential decree was also issued on 5 October 2004 and the decree said that they issued it because in light of the urgent need of the community and the effort to control HIV/AIDS epidemic.

And the decree empowers the Minister of Health in Indonesia to appoint a pharmaceutical factory as the patent exploiter on behalf of the government and this is and Indonesia also offers 0.5-percent as statement of royalty because they said they are having an economic crisis and they could not afford to pay more.

Now we see that countries are just beginning to understand what [inaudible] flexibility is all about. It is very legalistic. It is very technical. Civil society has played a huge role in the increasing of [inaudible] about the need to use flexibilities and we hear a lot of [inaudible] wanting to make use of the flexibilities.

Now while this is happening what we see is [inaudible] obligations emerging in bilateral free trade agreements that undermine the use of these flexibilities. In particular you see that in the U.S. free trade agreements.

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Now these are generally the [inaudible] provisions that you'll find in the FTAs.

One might, the first might lead from the other. But you will see that a lot of, some of these provisions, for example, data exclusivity. This provision was rejected outrightly when [inaudible] was being negotiated. But now it's coming back again in the bilateral free trade agreements.

This is coming back through the back door. It's not just an our piece. It's also on a lot of other issues of trade. Now just too quickly run through, the first one you find is [inaudible]. [Inaudible] that dropped regularly to authority from using the data that is generated by the original data company to authorize the registration of genetic products.

The second is the restrictions on the grounds on which compulsory license can be granted. You can grant it just on grounds of say, national emergency. You can grant it for in situations of extreme urgency or for public non-commercial use, but for, on no other grounds.

And [inaudible] Society and also the government fought very hard for core in [inaudible] to make sure that the grounds on which compulsory licenses can be issued were unlimited. The third provision you see is turning the drug administry authority into patent police.

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The Drug Regulatory Authority has the job of registering drugs. They do not have to monitor other product is patented or not. But now under the bilaterals this is coming about where the Drug Regulatory Authority's are being asked to become patent police. There will be extension of patent term. If there is delay in the granting of patent then the patent term is extended by that time period. Restriction or prohibition on [Inaudible] importation and require the grant of patent and new use of non-pharmaceutical products.

As you heard Anand speaking about how India has excluded new use of non-pharmaceutical products, now this is being required in bilateral free trade agreements.

Now what is the impact of these provisions? If you take the case of Malaysia, in 2003 we issued a Government Use Authorization and you've seen the information that I have shown with the data. That information is from the Ministry of Health and the prices of [inaudible] have dropped.

The number of patients that can be treated have increased. But we are also negotiating now. We are in the third round of negotiations with the United States, which means that we will most likely have to sit on this obligation.

And if we do take on this obligation then the impact is that we could issue a Government Use Authorization but

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perhaps the data exclusivity cannot make use of the product in the country. So you have the Government Use Authorization but you cannot register the drug in the country.

So what is the use of the flexibility? If you want to use your compulsory license then you [inaudible] are certain limited grounds. So these are the problems that are not only being faced by Malaysia but will also be faced by a lot of other countries that are currently negotiating, that have negotiated bilateral free trade agreements.

Now, I would like to just end with a slide showing where we were and where we are now. Before the [inaudible] agreement there weren't minimum standards on intellectual property rights. So we had like this blank sheet of slide. Then what we had at that time was an institution called WIPO, which is World Intellectual Property Organization.

Now, [inaudible] related to patent was the Paris convention and this slide has got very minimal obligations, and you only have to take on these obligations if you were a partner to this treaty, then came about the TRIPS agreement. Now TRIPS agreement was the first multilateral agreement that prescribed minimum standards on intellectual property rights.

And you cannot discriminate between sectors. So you cannot say medicines we do not want to patents. You had to grant patents. And this is applicable to all the [inaudible] countries.

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Developing countries then, when this was being negotiated at the [inaudible], the [Inaudible] countries said no they were not going to negotiate this. But they traded off because they felt that they would get some thing else in agriculture or other areas of trade.

So they said, okay, we'll take on this TRIPS obligations. But then they fought very hard for flexibilities. Following TRIPS, most standard-setting exercises taking place in the world intellectual property organization and this standard setting exercises our also in relation to patents. I do not want to go too much into what is happening in WIPO, but one of the very controversial agreements is some thing called the Substantive Law Treaty.

And this will take standards way beyond TRIPS Agreement and will remove a lot of the flexibilities that you have in the TRIPS Agreement. A lot of the standards that are being set also reflect the demands end of the developed countries. But these treaties are voluntary or they were voluntary. It means if you take on this, if you rectify the treaty then only then you will take on these obligations.

Now we have the [inaudible] agreements. Now this requires countries to rectify a lot of the WIPO treaties. Many of the developing countries have not rectified the WIPO, many of the WIPO treaties. But one of the obligations in the

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free trade agreement is that you have to rectify the WIPO treaties.

For example, Malaysia, there was immense pressure on us to rectify some thing called the Patent Cooperation Treaty. And statistics show that as soon as you rectify the Patent Cooperation Treaty, the number of patents in your country increases.

So this is where we are currently, and I think that if you are seriously concerned about access to medicines, we have to think of ways on how to scale back what is happening at the international level, at the regional level as well, and to scale back on intellectual property rights especially patents.

And perhaps you have to think about carving out of medicines from what is happening from the trend setting that is taking place on intellectual property rights. Thank you.

[APPLAUSE]

**FEMALE SPEAKER:** Thank you, Sangeeta. My last speaker is Jonathan Berger, who is a senior researcher on [Inaudible] Policy and Research at the AIDS project in South Africa.

**JONATHAN BERGER:** Thank you and good afternoon, everyone. Today I'm going to be speaking about two successful [inaudible] society campaigns in South Africa that

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manage to increase access to essential medicines for treating either HIV infection or AIDS related illnesses.

Both of the campaigns are relatively old and they happened quite some time back. The lessons I think that they teach us are so very relevant. The reason there have been no recent campaigns is not because there is no need for that.

But as many of you will know living in a country like South Africa where the President believes there is no link between HIV and AIDS, where the Health Minister who promotes the use of untested remedies instead of proven treatments.

We have many, many other issues that are occupying our time and many other legal battles. So while you may not be hearing any recent stuff coming out of South Africa on access to medicines, please watch this space. As soon as we have dealt with some of the other messes we are certainly going to be getting back to companies, companies like Abbott, companies like Merck, companies like Gilead.

The access that is in South Africa in that respect has not yet been won. The second point before I start, there is discussion this afternoon at 4:15 dealing with access to, dealing with the forgotten epidemic HIV/AIDS in prisons.

It's a shameless plug for a presentation. I'm making that, on a case that we are currently fighting on access to treatment for prisoners in South Africa. One of the 15

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clients on who's behalf we brought the case died last week. He was only put into treatment July of this year.

Some 20 months after his [inaudible] counts was identified at 87, died a month ago. Many others are going to die if the South African government doesn't get its act into gear quickly.

Today's presentation really focuses on three issues. Firstly, I want to sketch a little bit about the South African context because I think before one can understand why certain actions were taken or not taken it is important to look at us for what other particular access concerns that we have.

What is the [inaudible] political context? Why are some Africans acting and why are others not acting? And then also what is the constitutional flavor within which we operate?

Then the two case studies that I will focus on very briefly. The first is [inaudible] and other [inaudible] Boehringer-Ingelheim, using competition law to increase access to three anti retrovirals in particular. And then the second case, once again using competition law to challenge the excessively priced essential anti-fungal drug [Inaudible] an [Inaudible] drug.

So while much attention is focused on patency, I don't believe you must ever lose sight of the fact that the

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issue is not necessarily patent protection. The issue is no competition in medicines.

Patents have a significant role to play in that, but in many cases it's not, there are no patents but there is no competition and prices remain as high as they ever were, and then to conclude a few thoughts on where we need to go.

The access concerns in South Africa are really twofold. Firstly, the issue of excessive pricing and that is something that has improved over the years but certainly hasn't been resolved.

Prices are still too high and there is much room for those prices to come down. A second point and this links to the point that was made this morning in the presentation on Rwanda and that is the issue of sustainability of supply.

We are very concerned that even with prices maybe the lowest that are available, may not be the lowest that they can ever go to, but maybe the lowest that are currently available having a single supplier in respect of any anti-viral is not a way to insure sustainable program. One needs sustainability of supply.

We have seen in certain circumstances in South Africa [inaudible] drugs. Countries like Botswana, that are entirely relying on patented drugs, have run out of drugs and we have correspondence in our possession where a letter sent by GlaxoSmithKline to the government of Botswana saying, We

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are unable to provide you with, I think it was ADT at the time.

Please contact Aspen Pharmacare in South Africa and they will provide you with the drug. This is not sustaining the fact that as a result of the [inaudible] case Botswana has a legal right to import drugs from a company like Aspen in South Africa without having to get a letter authorizing them to do so from GlaxoSmithKline.

In terms of the political context, what is very important to understand is that there was and has been and continues to be very little movement on ensuring that they're A, is a proper regulating framework to ensure that drugs are affordable, and B, the use of the limited provisions that we have in our law.

Sangeeta spoke about the Malaysian example of government use, the government use provision. We have a similar provision TRIPS compliant. It is consistent to our constitution and yet government refuses to make use of that provision time and time again.

They don't even make, threaten the use of that provision. They simply act as if their hands have been cut off and they are unable to act. In that context the leadership has been shown by civil society and civil society has been forced to look for creative ways to make use of an imperfect but still a possibly useful legal framework.

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That legal framework that I'm talking about falls within our broader constitutional framework, one in which sets economic rights are expressly protected.

The rights of access to health care services, a constitutionally guaranteed right in the South African constitution, which places [inaudible] obligations on the states to ensure that people are able to get access to health care services and then in this case as our courts have held that access to health care services includes access to essential medicines.

So even in cases where government is not obliged to provide the medicines free of charge to everyone, certainly to those who the absence of free drugs would not be able to afford it.

They do have an obligation. For those who have money the obligation on government is to ensure that the drugs are affordably priced. So where provisions exist that can be used to just make prices there is a constitutional obligation to make use of those provisions. We have not seen that happening.

The final point that I think is important under our constitutional framework is that all legislation has to be interpreted in line of the socioeconomic [inaudible] provisions and all provisions of our Bill of Rights. So it's not good enough to say, well this is an act that deals with

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competition law, which deals with unfair trade. This deals with intellectual property.

It has nothing to do with human rights. Under the South African constitution and certainly under international human right's law, there is an obligation to interpret the provisions on patents, the provisions on competition law in compliance with fundamental rights of access to health care, of rights to life and things like that.

The two case studies in, very briefly in summary, the first one is focused on three essential anti retrovirals. At the time all three have been patented, ADT, CTC, and Levopien [misspelled]. The three of them are three of the seven essential anti retrovirals that are provided in the South African public sector anti retroviral treatment program.

At the time that case was launched, the first case is launched there was no generic competition for any of these drugs. There is some now and I'll describe that a bit later. And ADT has subsequently come off patent.

And the focus of that case is on excessively priced, private sector prices. We focus on the private sector because the public sector at that point was not providing treatment at all to anyone. So the political prices were certainly not prices that you could challenge.

The second case deals with the antifungal drug Amphotericin B, an off-patent drug that there were no generic

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or equivalents on the market. And one has to ask the question where are the generic companies when it comes to many of the drugs that are not on patents. Drugs like [inaudible] is not patent-protected in South Africa. Drugs like Amphotericin B, and yet you have not seen generic versions of those drugs on the market. They need to come to the party as well. The case dealt both at the public and the private sector prices of Amphotericin B.

I see my time is starting to run out, so I will rapidly go through the two cases. The first case was based on the provision about competition law, Section 8A, which talks about engaging in excessive pricing to the detriment of consumers. So one has to prove excessive pricing, one has to prove detriment.

And those two are not too difficult to prove in our case. We were quite blunt in the case. We said that prices that they were charging was direct were directly responsible for the premature, predictable and avoidable deaths of people living with HIV and AIDS.

Too much of this conference is about tiptoeing around the issues. We don't really speak clearly about what the issues were. In this case, we were up front. We said, "Your prices are killing people. You need to lower those prices. We're going to force you to lower your prices."

[APPLAUSE]

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We took a very conservative approach to this case and we really tried to bend over backwards and to say, well, even if you consider every thing that you say you have to consider, your manufacturing costs, your research and development costs, your licensing costs, and we'll be decent guys, we'll even give reasonable profits.

We don't believe you are the International Red Cross. You do need to be in business. But even when you take all of that into consideration, you cannot justify the prices that you are charging. That is the case that we made and the case that we hoped that they would come to court to answer.

The matter was settled in December 2003 before it was going to be referred to our competition tribunal for adjudication. Many of the complex legal issues remain unresolved.

But for us we made the bigger decision to take. On the one hand we wanted to push forward and get some good case law and make sure that you had a solid precedent that you could use again. But on the other hand lives were in the balance and we really needed to get affordable medicines out there.

One of the benefits of agreeing to a settlement was that on November 2003, government had already published the anti retroviral treatment program and it was essential that generic medicines were part of that program.

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The complaint was an excessive pricing complaint. It resulted in a licensing solution. And you can on, the slide you can see the terms and conditions that we ensured are applied to every licenses that are granted.

In respect to GlaxoSmithKline, there was an agreement that we would grant at minimum four licenses and Boehringer-Ingelheim three licenses for each of the drugs.

This slide you can see, these are private sector prices are still unreasonably high. But you can see the prices differentials are quite great from the prices of the medicines at the time the complaint was lodged as opposed to the cheapest generic available in private sector today, ranging from between 57.6-percent to as much as 88-percent reduction on the [inaudible].

Finally on the Amphotericin B case, this is a case that worked hot on the heels of the [inaudible] case. And we really didn't even need to file papers with our competition authorities.

A series of letters that went back and forth between us and the lawyers of Bristol-Myers Squibb, they thought they could teach us a few lessons in competition law. We told them if they wanted to engage in that kind of debate that we'll deal with them in court, but for now we wanted them to justify their pricing policy.

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They were not able to justify their pricing policy. Instead what they did was go reduce their prices in the private sector by 85-percent and the public sector by 80-percent. At the time the public sector price for this drug, a crucial drug for treating cryptococcal meningitis in the first two weeks was \$20 per patient per day. At the end of the matter it came down from \$20 to \$3 a day.

[APPLAUSE]

To conclude, I think it's important that the lesson that one can learn is that one doesn't have to sit back and wait for governments to take the lead. One, most of our governments are scoundrels.

They are not going to act. They are quite happy to stand back and to blame either George Bush, to blame the World Trade Organization and, in many respects, they are correct when they say that. But they don't take responsibility themselves.

They really do need to act. They need to implement what international law allows them to do and they need to move forward before they have the lives of their own people on their own hands. And to end this, I'll leave this final slide for you, which needs no explanation. Thank you.

[APPLAUSE]

**FEMALE SPEAKER:** Thank you, Jonathan. We're now going to head over to our colleagues, who have each received

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a set of questions, written on cards. So each take a few minutes to respond to all of their questions.

**MALE SPEAKER:** Yes, I don't know. Should we start with [inaudible]? Is she comfortable [inaudible] read them [Inaudible].

**FEMALE SPEAKER:** The first question I have is, how do they [Inaudible] data exclusivity provisions and restrictions and bilateral free trade agreements affect countries ability to use [inaudible] prequalification to expedite drug approval?

If I'm not mistaken, they [Inaudible] data exclusivity provisions do not affect [inaudible] prequalification. What it does is, you see, before a drug can be used in a country it has to be registered in a country. They have to obtain marketing approval.

So what the [Inaudible] data exclusivity provision actually does is that the generic version usually relies on the test data, the clinical data that is created, generated by the original company to get marketing approval for the product. So for the generic to obtain marketing approval it just has to show that it is equal to be [inaudible] original drug.

It does not usually generate its own test data. So it gets registered on the basis of the first drug being registered. And so you have data exclusivity provisions that

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is to say, patent holder has exclusive rights over its data for, say, five to 10 years.

And I think that's what countries are now implementing within five years to 11 years. If that is the case then generic versions cannot enter into the market during that period.

And this also applies not just too patented products. This also applies to one patented product. So even if the product is not patented to the first product but the patent holder, but the producer has got rights over the test data more generic can enter into the market and so this is a problem when you talk about data exclusivity provisions.

Now, the second question that I have is on TRIPS [Inaudible]. [Inaudible] I should ask the question. TRIPS [Inaudible] are not regional [inaudible] intellectual property rights to prevent [Inaudible] in bilateral and usual trade agreements and in [Inaudible] medicines as the problem groups that they are.

Well, definitely [inaudible] are not good enough because right now we have the flexibilities. But there is so much pressure not to make use of the flexibilities. You can see in the tape that I presented in the Malaysian case it was just because the Ministry of Health was [inaudible] that a Government Use Authorization would be issued.

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The Cabinet, during the Cabinet meeting, the prime minister himself said, "Yes we're going to go ahead and do this, because there is this [inaudible] declaration and it's our right to do it." Because of that, we had the Government Use Authorizations.

But a lot of countries, there's so much pressure not to make use of the TRIPS flexibilities. In fact, as soon as it is heard that you want to make use of flexibilities, a lot of pressure from the industries, from the other ministries for you not to avail yourself of those flexibilities.

You take the case of Indonesia, what I understand in Indonesia is when they wanted to make, issue the Government Use Order, what I've been told is all of these people who are aware of the fact that Indonesian government was going to do this. They were told that you have to keep this a secret. It's going to come under the Official Secrets Act or some thing like that.

So that was the case in Indonesia because they knew otherwise there would be a lot of pressure on them not to do so. So there are a lot of flexibilities but we just cannot seem to use them when we really need to do so.

And then there's pressure for us to adopt [inaudible] and then to limit the flexibilities that we have. Now in relation to the argument that is referred to by patent holders is that we need more higher standards of patents.

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We need data exclusivity provisions because we need to recoup investments. You know there is a lot of money which has gone into R&D, et cetera.

But if you look at the data we see more and more patents being granted. But the innovations, the new chemical entities that are actually being researched, that are being developed are growing very few. So it does relieve the problem idea that if you have the patents, if you have DE then you are going to have a lot more new medicines, new innovations.

And they recently thought which was the issue by the [inaudible] Commission on Intellectual Property Rights Innovation and Health and the report the Commission identifies that patents in lower income countries does nothing for innovation.

And they have, one of the recommendations is that companies should not apply for patents in lower income countries. So definitely to answer the question flexibilities is not enough. We have to think about actually taking TRIPS out of the [inaudible].

[APPLAUSE]

Because it's not just in relation to medicines, we're talking also in terms for the development, because developing countries are users of intellectual property rights, whereas

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developed countries are exporters of intellectual property rights.

So what happens is that even, they talk about access to technology that is being hampered. If you take the case of India one of the major reasons they're also able to develop their pharmaceutical industry was because they had no product patents in the country between 1970 and 2005.

So I would think we do need to look at ways on carving out, if not for other areas but at least for medicines carving out from the [inaudible] system because this is an essential item and you cannot trade away with this essential item. Thank you.

[APPLAUSE]

**FEMALE SPEAKER:** Thank you. I just want to ask [inaudible] to please really summarize their questions because there's millions of questions and it's really critical that we try and get through quite a few of them. So please. David?

**DAVID:** Yes, there are three questions. The first one, what are the generic companies in India doing for people living in [inaudible]? [Inaudible] in India and in the backyard 20,000 patents are [inaudible]. It is shameful.

That is not a question. [Inaudible] there is progress to be made and we have to do a lot in India about it. So that is in fact [Inaudible] yesterday here. The

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second question is from Robin Stern from the U.S. [Inaudible] for essential medicines.

What position has the generic industry taken with the regard to the production of intellectual property rights and [Inaudible] civil society better access? Has that changed over time? They have gotten an interesting question.

The [Inaudible] industry is like any other industry. They are interested in making profits. There are no doubts about that. Now what has happened [Inaudible] 1995 to 2005 is that there has been a split within the [Inaudible] industry.

One is [Inaudible] represented by in fact the [Inaudible] organization of the industry that have [Inaudible]. [Inaudible], European and American multi-nationals. And that has been an organization of pharmaceutical producers in India [Inaudible] the U.S. and then [Inaudible] some the of European [Inaudible].

Then there are two Indian Associations, the Indian Drug Manufacturers Association, [Inaudible] industry. And we have Indian Pharmaceutical Alliance, which is the research and development in the industry and used to be generic but now actually it is actually getting into alliance with the U.S. and European [Inaudible] company in Germany. Some in the U.S. and [Inaudible] is part of that.

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And they are exporting [Inaudible] production. Fifty-percent of the production is for the U.S. market. They are not interested in the [Inaudible] people with HIV. They [Inaudible]. They also want to make a lot of [Inaudible]. So we are more [Inaudible].

It is not about the Indian or non-Indian. It is about generics. Okay. Then there is the question that [Inaudible] from the United States, to understand the [Inaudible]. The U.S. [Inaudible] for [Inaudible] India and not to [Inaudible] of AIDS [Inaudible] in Nigeria or lose all its foreign aid. Can Ms. Clinton and Ms. Gates [Inaudible] to opinion to stop this.

It is a very important question. You hit the nail on the head. Mr. Clinton and Mr. Gates should [Inaudible] the U.S. Administration to stop using [Inaudible] and [Inaudible] in any cases altogether, and the hypocrisy [Inaudible] because it is all right to talk about and it is very good to talk about harm reduction, but when you start talking about politics which affects U.S. [Inaudible] industry and the U.S. multi-national pharma industry.

[APPLAUSE]

**MALE SPEAKER:** Okay a few questions now to Jonathan.

**JONATHAN BERGER:** Thanks. I have quite a few. I'm going to try and get through them quickly. A question from [inaudible] from South Africa, talking about a definition of

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National Emergency and the TRIPS in the special compulsory licensing, and isn't AIDS a National Emergency?

Certainly under the [inaudible] Declaration, it's clear that the HIV/AIDS epidemic is considered a National Emergency. But over and above that countries are free to determine for themselves what an emergency is.

In any event, the issue of National Emergency is only relevant to the process by which compulsory licenses are granted. It certainly does not affect the rights to grant such licenses.

The only thing that it, there is an emergency you don't need to enter any kind of prior negotiations. You can merely step in and issue the licenses. But the right to grant licenses is not dependent on the emergency whatsoever.

The second question is from Steve Hubbard from Canada, talking about the disconnect between the progressive [inaudible] Constitution that we have and a terrible record of inaction on the part of government and what are the factors leading to this lack of accountability?

It's an incredibly difficult question to answer in a couple of moments. I'll just throw out a few issues. I think we certainly have no decent opposition.

In Parliaments, the only opposition is opposition that comes from civil society itself. We have an electoral system of strict [inaudible] representation, which means that

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Parliamentarians are accountable to the party bosses and not to the people who vote, got them into Parliament in the first place.

So we have a Parliament that in many respects acts as a rubber-stamping agency. And if one wants evidence of how loyalty is prized over anything else, one needs to look at the very long tenure of our Minister of Health to see that if you're loyal, if you do what the boss wants you to do you will keep your job no matter how much you wreck the economy, no matter how much you destroy the lives of people living with HIV.

[APPLAUSE]

**MALE SPEAKER:** Two more questions. [Inaudible] from the USA. Amphotericin B is not available in South Africa. {Inaudible} alternative agents is used where it wasn't available in the public sector. As far as I understand, treatment is only being provided by the use of [inaudible].

At the moment now that it is available and I'm not sure how widely it is available. It should be available in every public health facility. The first two weeks of treatment will be with Amphotericin B followed by [inaudible] maintenance. If [inaudible] itself goes back to a long campaign made by the [inaudible] to bring the price of that drug down. So we'll be seeing [inaudible] tying together quite nicely.

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[Inaudible] from South Africa says that it is not good that the Minister of Health is not available various options to people living with HIV. What more still needs to be done?

I think it is important to recognize that there has been progress in the developments in South Africa, but that it really has come at the end of the barrel of a gun.

The government has reacted, it has really not [inaudible] from the front. The issue of making available various options, I think to me raises very uncomfortable concerns about what I call the false [inaudible] of choice where unproven remedies are presented as equivalents to registered treatments.

And I think that perhaps is the biggest danger, is where we've seen South Africa at the moment where under the guise of human rights language we talk about choice but we don't actually give people the choice information.

We don't enforce our laws correctly to ensure that people are able to make informed choices. So that they know when they take a particular medicine that it has been approved for the use and that it is not mere wishful thinking that a particular traditional remedy may have the desired effect.

[APPLAUSE]

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And then my final question is from Dr.[Inaudible] from [Inaudible]. There are two questions here. The one I'm going to focus on is talking about the [inaudible], questioning the link between HIV and AIDS. How has this progressed over time or how has it affected access to treatment in South Africa?

Certainly it has affected the patent [inaudible] so that [inaudible]. The gap between those who have treatment and those who need treatment is rising in South Africa. It currently sits probably at more than 500,000 people.

And for as long as we do not resolve or we do not clear up the mess that has been caused over the years by the denials, people are going to remain confused.

Health care workers are not going to know what to do and political leaders at lower levels are not going to know what is going to satisfy the party bosses. Should they be pressing ahead very strongly to implement this treatment or is that going to cost them their jobs at the end of the day.

Until we have clear leadership from the top saying that HIV causes AIDS, that anti retrovirals save lives, until we have that this program is not going to be implemented in the way which is going to turn this epidemic around.

**MALE SPEAKER:** Okay, thank you very much. I will and we still have a lot of questions. It will not be possible to answer all of them. I have a couple of requests here. One

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is to read a very short statement that has been made by a coalition of NGOs saying access to treatment, people before trades. I think they are passing are here to sign this.

"We the participants attended the 16 International AIDS conference, [inaudible] that our governments and trade negotiators [inaudible] from the potential [inaudible] consequences of bilateral and regional trade agreements on public health.

These agreements enforce even stronger standards of intellectual property protection than imposed by the [inaudible] or TRIPS Agreement. [Inaudible] intellectual property rules are already making it difficult for countries to access affordable medicines.

[Inaudible] to a country must commit to a moratorium on any new bilateral and regional trade agreements that include provisions involving intellectual property rights and medicines.

All the [inaudible] members must agree they will not enforce any provision in the manner contrary to the 2001 [inaudible] Declaration on TRIPS and Public Health in such agreements."

And so this is, I think, circulating and I know that already, some important people already have signed it as well. And also there is a gathering just around the corner

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here, this floor at 1 o'clock for people who want to march on this issue.

There are a lot of questions on research and development versus compulsory license. [Inaudible] we won't have time to answer this, just maybe would like to say that there's a lot material that has been written on these issues showing that actually 90-percent of the world pharmaceutical market is in the rich countries that R&D has been always designed [inaudible] rich countries mainly and that if you have these medicines in the developing countries, it is because actually there was a need first in the rich countries.

But I [inaudible] have time to answer these questions because we are already getting close to the end of our session and maybe I would just like to ask each of them to close the discussion with a couple of minutes maybe answering the last questions that they have.

**FEMALE SPEAKER:** Just before the panelists is just one more question. The Dr. [Inaudible] in South Africa. [Inaudible] to provide second line treatment to her patients and therefore [Inaudible] this meeting should afterwards [Inaudible] the pharmaceutical company [Inaudible] where we should go [Inaudible] get the prices and stop [Inaudible] pressure and [Inaudible] want to do the right thing. So that

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is [Inaudible] question. Those that want to proceed with that [Inaudible] outside the hall when we get done.

**MALE SPEAKER:** So, the panelists please, Alessandra?

**ALESSANDRA NILO:** Thank you, [inaudible]. The question that was addressed to me was about [inaudible] we have facing this equation. [Inaudible] and what can we do at the country level. And I think that it was mentioned here that [inaudible] we are facing.

Now we have also to prepare more many spaces to deal with situations. We're not [inaudible] was to prepare the legal systems [Inaudible] country, to deal with these indication of patent laws and to know how to address the [Inaudible].

[Inaudible] concern about [Inaudible] because we are [inaudible] people who are deciding about this law, they are not well prepared. They just don't know what we are talking about. So this is one point.

The second point and to me really complex is how you can solve that [inaudible] company laboratory are promoting promoting around the world about what means generic drugs.

So there is a [inaudible] even among people who are taking medicines, who are needing medicines, about generic drugs because the markets so hard saying that generic drugs means bad drugs.

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So it's something you need to fight back and now Abbott is talking really badly about the generic drugs we are [inaudible] and this is something we are, we need to strategize, how can you [inaudible].

And the other question is that we need to prepare our activists and our people on the ground because [inaudible] HIV and AIDS [inaudible] was a matter of public health in the 90s. It was a matter of human rights. [Inaudible] basically asked [Inaudible] commerce.

[Inaudible] people who had been [Inaudible] saying all this complexity and [Inaudible] we are facing here. So I think each country needs to find out their possibilities but I think that we altogether need to work in order to make sure that information will be available in our capacity and skills will be also available to everybody who is needed [inaudible]. Thank you.

**MALE SPEAKER:** [Inaudible]. I will quickly answer the second question. One is actually [Inaudible]. The generic [Inaudible] studies for the products [Inaudible]. I am not going to take that [Inaudible]. The second question is very interesting. [Inaudible] has recently announced they are filing patent applications to [Inaudible] in India as well as [Inaudible] voluntary licenses.

Could you address this? How could it affect the access to drugs? Well [Inaudible]. [Inaudible] didn't have

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a patent in India. They are actually making, actually entering into voluntary licenses with India company. There is not a [Inaudible] of the patent laws. Because some of the Indian companies, they are afraid [Inaudible] patent to be granted, then they would be knocked out of business.

And therefore would enter into a [Inaudible] licensing. Not it means that the [Inaudible] neutralized. So it is very [Inaudible] a crisis in the long term. And it is anybody's guess how long [Inaudible] in completely free of being taken over or [Inaudible] with the [Inaudible]. So we [Inaudible] seven years by multinationals to ultimately not only [Inaudible] to agreements but we actually measured them [Inaudible].

**FEMALE SPEAKER:** I have been asked to address this issue of voluntary license versus compulsory license. [Inaudible] voluntary license let a patent holder voluntary grant the person who wants the license voluntarily. Okay compulsory license what is that? It is where the government issues a license for its own use or for to a third party, license [Inaudible] without the consent of the patent holder. Now that is a compulsory license.

Now what is the difference? Why not go for voluntary license? Why go for compulsory license? If you look at how the voluntary license have come about. Let me take the [Inaudible] case. After the Government Use Authorization

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ended in 2005, the Ministry of Health said the patent holders are very [Inaudible]. We so perceive that prices of patented drugs dropped.

That also I understand if given a voluntary license, which they would not have done if we have not issued a compulsory license first. So that is how that voluntary license came about. We are not privy to a lot of details as to what are the contents of the voluntary license and how much royalty is to be paid.

You take the [Inaudible] example as well. The voluntary license and reasonable terms that came about with the voluntary license only came after the competition; commission came up with certain decisions against the patent holders. Then we had voluntary license [Inaudible]. Otherwise the royalty that was being charged was 30-percent and it got reduced to what, 5-percent now?

So this is events that have actually forced patent holders to issue voluntary licenses. You take the recent example of [Inaudible]. When Asian flu was hitting a lot of countries, Roche came up and said [Inaudible] would not grant licenses.

We would manufacture. And every day the position changed. And as more countries said they would issue compulsory licenses, then they said, yes, we will also issue

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voluntary licenses as well to prevent countries from setting a precedent by issuing compulsory licenses.

So we see that patent holders are not voluntarily coming up and granting voluntary licenses. And if they do grant it and if they do grant it on terms, for example, you can use it in the country but you can't export it.

The royalty is very high on things like that. So that was just a point I wanted to make. The other question is in relation to this piece of [inaudible] Agreements. Very quickly, the [Inaudible], the free trade agreement that are being signed.

First is the investor [Inaudible], where the investor can take the state to court when investor tribunal has been set up. Now, I see intellectual property rights has been defined as investment so you take away because investment is defined very broadly so you take away certain rights that can [inaudible] and then the country would have to give compensation to the investor.

Now, in a lot of, some of the future agreements, compulsory license has been excluded. But it's just open to the imagination on what grounds they can actually use this investor [inaudible] and try to gain compensations from countries.

The other [inaudible] that has been set up is country to country. And what we see is the use of non-violation

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complaints. In the WTO, there is currently a moratorium on the use of non-violation complaint when it comes to intellectual property rights.

What is non-violation complaint? That means that even if a country has got a provision that is required by the FDA but [inaudible] and it has the benefits that they can obtain by having that investment then they can sue under non-violation complaint. So this, is just very briefly before I just [inaudible].

**MALE SPEAKER:** I don't have any more questions, so I am just going to have three concluding comments. I've got three messages, one for developing country governments, one for the pharma industry, the innovators and one for the generic companies.

To developing country governments, they really need to get their frameworks right. And to do so in a way which enables the state to act which enables civil society to act and which in enables the generic companies to take action themselves, although that may be wishful thinking on this, in respect to the generic companies.

For the pharma industry, we really need to license generic companies on reasonable terms, none of these terms that Sangeeta has been talking about. And if they don't do so on reasonable terms, we will determine whether those terms are reasonable and if we're not satisfied with that we will

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compel them to do so by getting to court. And that's the message in South Africa for Abbott and for [Inaudible].

[APPLAUSE]

And then for the generic companies, really, it's also time to deliver. There have benefited from a lot of the work that we have done asking Pharmacare in South Africa which stocks have soared as a result of a of the work that we have done.

And it's time that they bring much-needed products to market, that they bring new [inaudible] combinations, that they bring pediatric formulations, that they bring products like [inaudible] and Amphotericin B.

We need those products on the market. They can't sit back and relax and enjoy the fact that most of the attention is directed at the innovators and not at them. Thank you.

[APPLAUSE]

**MALE SPEAKER:** Well, I think we had a very rich way of saying that actually in this globalized world we had [inaudible] countries and continents who are actually living in the same type of problems and that the implementation of the TRIPS Agreement and now our free trade agreements are really not helping the access to medicine question.

So I think we are in, we just ended a transition period and if we compare it to the last AIDS conference where India was still not compliant with TRIPS, we are now in a

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situation where India is also TRIPS compliant so we are actually at the beginning of a new era.

And we see that the fight is only starting to try to improve the access to medicine in the world and with the second line [inaudible] crisis that is coming up where most medicines are patented.

I think that in two years when we meet again in another, for the next AIDS conference we certainly would have a long way of battles before use with court trials and discussion about if TRIPS has or not to change and if trade agreements have to go on a moratorium on that. And so I'm sure that we will have strong debate.

But certainly, I would like to thank all of the audience for the questions and panelists will be here available for the ones who had not had the chance to have the announcer. Now I will pass the word to our chair.

**SIPHO MTHATHI:** Thank you. I think you've summarized it well. [Inaudible]. People are going to be put in front of profits. Thank you.

[APPLAUSE]

[END RECORDING]

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