

**THE INSTITUTE FOR TRADE, STANDARDS AND
SUSTAINABLE DEVELOPMENT**

**THE FUTURE OF U.S.-BRAZIL TRADE RELATIONS IN
THE SHADOW OF BRAZIL'S PIRACY
OF AMERICAN INTELLECTUAL PROPERTY**

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LAWRENCE KOGAN: Good morning and thank you for attending our press conference about the future of U.S.-Brazil trade relations in the shadow of Brazil's piracy of American intellectual property. My name is Lawrence Kogan and I am with the Institute for Trade, Standards and Sustainable Development. We're a nonpartisan, nonprofit organization devoted to promoting a positive paradigm of sustainable development.

We've convened a panel of experts in the area of intellectual property rights to talk this morning about a proposed bill adopted by the lower chamber of Brazil's legislature that attempts to basically break pharmaceutical patents. That includes not only the products but also the processes by which they are made. I will be introducing five esteemed panelists shortly, that will be talking about different aspects of this issue. These drugs have been used to fight AIDS in Brazil, and Brazil has a very admirable AIDS treatment program and has been able, with the help of such drugs, to stem, to a great degree, this AIDS pandemic.

But the issue that we're talking about today is not really about AIDS, it's not really about how helpful the drugs themselves are, but we're talking about the fundamental concept behind this, and that is intellectual property protection and how there is a procedure within the World Trade Organization agreement called TRIPPS, by which a government, in certain circumstances, may pursue flexibilities to allow for suspension of some of the strongest intellectual property rights protections in order to address urgent public health needs and other commercial concerns.

I would like to begin this morning by introducing Ms. Nancie – Mr. Slavi Pachovski, rather, of the Institute for Trade Standards and Sustainable Development, who will be discussing some of these broader trade issues.

Thank you.

SLAVI PACHOVSKI: Thank you very much for coming. I'm honored of course with your presence here, because we believe that this is an extremely important issues and is an issue with some kind of emergency, because if this trend proceeds, it will be a global pandemic of AIDS that will grow uncontrolled, mostly because the Brazilian move will destroy the whole legal order that is the basis for developing new drugs and continuing the research.

The move is prepared by the Brazilian government by several statements previously, and it is kind of explained to the public as a concern for the health of the sick and the poor. The paper that we wrote, and I'm sure that you all will get it, has a title, "The Wolf and the Stork." We want to point out that this is not about the sick and the poor that we're talking here. We, as American companies, or representatives of this great nation, that it is the biggest single contributor in global AIDS campaign fighting the AIDS. We are bringing the drugs. The pharmaceutical companies over there are bringing the drugs. The stork helped the wolf when it was in a difficulty in the famous fable of wolf and the stork on this, taking out the bone out of his windpipe, and then

when he asked for compensation, the wolf jumped on him. This is exactly what is happening, and very few people at the moment perceive Brazil as the wolf. And we want to point out, and I would like very much you to look at the paper – more is coming; this is very short presentation.

Brazil is developing a global pharmaceutical industry. It is already poised to become a global power. To have a drug put on the market, the average price is about a billion dollars. Those guys want to jump over this step and steal this kind of wealth. The research and development is the single biggest portion in the price of any medicine. And AIDS has a very large market on this. They are talking not only to supply the Brazilian market, but already they have talks to supply Africa and Asia. The Brazilian president, even before enacting this legislation on TRIPS, held press conferences on these issues, and there are ample evidences that Brazil is poised to become a global power in the pharmaceutical industry.

By developing the so-called generic drugs – these are not generic drugs; these are stolen drugs; these are drugs built on stolen patents. The whole process will be – (unintelligible) – on this because there will be no investor that will support the research and development needed for the pharmaceutical company. Plus, the global trade means order. There are rules to follow. By this particular legislation, Brazilian government says that they do not want to follow the established order, because there is a procedure to follow if there is a national emergency, if there is an epidemic, if there is an acute situation, eventually to abrogate, to issue compulsory licensing, to discuss with the company what kind of drugs will be attacked or expropriated, the patents, to make the necessary replacement drugs. Nothing of this is – (unintelligible). Brazil, by proclaiming certain drugs non-patentable, is attacking directly the basis of the order. They don't want the order; they want to be a world power on this. And we want to go down to Brazil and to check it with firsthand interviews and contacts with their politicians.

They are really poised, because their conversations that this is linked to some kind of debate around American subsidies to cotton – Brazil is also a superpower in cotton exports. We want really to test firsthand what is going on in Brazil because we believe that this is beginning of a major crisis. If Brazil is allowed to set such kind of example to other countries – because India and China also have similar ambitions to become center of so-called generic drug industry. The whole pharmaceutical industry, a whole sector of the trade, will be really destroyed and we shall have a totally different system.

Now, this is a war of the jungle that they are proposing us, to say that the medicines, the drugs are not patentable. Plus, they do not center this on a single drug – a vast array. They are talking not only AIDS; they are talking to tuberculosis, they are talking any kind of related disease. AIDS, as you know, attacks the immune system. So particularly when a skin disease is related to AIDS. Brazil is talking that they have national emergency. They didn't proclaim one. We didn't see any legislation, because if you proclaim national emergency, you say how long it will last, what do we do for prevention, and there's a whole array of questions on this, but they have a rate of AIDS similar to what is in United States. United States have 0.5; Brazil has 0.6, Swaziland, by

their own admittance they have 36 percent. They didn't proclaim a national emergency on this. Brazil is talking national emergency. So for us this is not a national emergency. This shows the truth of the wolf chasing the stork.

I will be glad to answer questions if you have. I don't want to take the time of other panelists here, but I am really very appreciative for your attention and would like to follow up on this issue.

MR. KOGAN: Thank you, Mr. Pachovski.

Next I'd like to introduce Ms. Nancie Marzulla, president, Defenders of Property Rights.

NANCIE MARZULLA: Thank you. I'm delighted to be here this morning. Defenders of Property Rights is a national property rights organization, as the name suggests, and we have been fighting to protect property rights since 1991. And for the past almost 10 years now we have expanded our efforts to include the protection of intellectual property rights, creating a bridge between real property rights and intellectual property rights, because in today's modern world we recognize that no one's property is safe if any property, including any form of property is not protected.

One of our greatest presidents, Abraham Lincoln, in fact once said in a speech that property is the fruit of labor. He also said, and I quote, "Property is desirable. It is a positive good in the world. Let not him who is houseless pull down the house of another, but let him work diligently and build one for himself, thus, by example, assuring that his own shall be safe from violence when it is built."

Brazil today stands in the shoes of the houseless person pulling down the house that another person built. But as Abraham Lincoln warned over a century ago, stealing another person's property is a short-term strategy. No lasting security and no lasting solution for national problems ever comes from theft. Brazil has been on the U.S. trade representative's watch list for intellectual property rights violations since 2001. Rather than cleaning up its act, however, and acting as a responsible trading partner worthy of favored trade status, Brazil in fact continues to escalate its violations. Worse yet, we hear that Brazil is cutting a deal to fence its stolen goods or pharmaceutical products to South Africa.

Now, I have a suggestion for Brazil. If it really wants to steal something from the United States, I propose that it steal something far more valuable than our pharmaceutical products. I suggest that it steals our Constitution, specifically Article 1, Section 8, Clause A, which is the foundation for all of our copyright and patent laws.

Admittedly, the United States is one of the richest countries in the world today, and we are the reach and the breadth of – the riches of our country have exceeded, I think, anything that the founding fathers ever could have envisioned, but the foundation for our prosperity and the engine for our nation's creativity rests on our vigorous

protection of private property rights. Who knows what Brazil could accomplish if it would start protecting property rights.

Thank you.

MR. KOGAN: Well, thank you for a nice discussion on that subject matter. I would like to introduce now Mr. Reid Cox of Council for the Center of Individual –

REID COX: Freedom.

MR. KOGAN: Freedom. I couldn't have said it better myself.

MR. COX: Good morning. Thank you for your attention.

The Center for Individual Freedom is a nonprofit, nonpartisan advocacy group here in the Washington, D.C. area, and we're big protectors of intellectual property and also of the free market. We certainly echo the concerns that have been stated on the panel with Brazil, but we also have the separate concern, quite frankly, that the U.S. has not taken action to provide some incentive for Brazil to act in the proper way in protecting intellectual property rights. I think the paper that has been introduced in this panel – and Nancie Marzulla and others have made it very clear the problems that Brazil is having with protecting intellectual property.

And I guess I'd like to add to that the fact that the government doesn't have any incentives to protect intellectual property rights. In fact, over the past two years, government spokespeople have said things like this in response to calls from the United States to protect copyrights and patents. And Brazil's response was, basically, we're trying, and they're – quote – “Counterfeiting and smuggling costs the country the equivalent of close to \$10 billion a year in lost tax revenue.” And I think it's from comments like this you can see that when Brazil sees the bottom line, they're willing to make some move on protecting intellectual property rights. The problem that we have with patent protections on AIDS drugs is that Brazil sees the bottom line being in favor of breaking patent protection on AIDS drugs because they can then turn around and produce, quote, unquote, “generics” that they might be able to sell to South African countries, while at the same time not having to pay the costs of these drugs to supply for their free AIDS treatment program in Brazil.

So what the center is urging the administration to do is to really seriously consider imposing trade sanctions or not renewing Brazil's preferred trade status with the United States, so that there is going to be some cost, some incentive that Brazil has to make sure that they understand there are consequences when they break patent protections on AIDS medications. And so I think that that's really what we're here to do is to show that there are incentives on both sides of this equation and that there's truly a problem that's going on in Brazil but there's also a problem that's going on here in the United States because the United States government's attitude towards Brazil patent violations so far has been

to say, stop or we'll say stop again. (Chuckles.) That's not providing an adequate setup for Brazil to actually start protecting American patents.

Thanks.

MR. KOGAN: Thank you very much for your excellent presentation.

I'd like to next introduce Mr. Scott LaGanga from Americans for Tax Reform.

SCOTT LAGANGA: Thank you. I'm delighted to be here today and to address a topic of this magnitude, speaking from a different setting than what my colleagues are discussing in terms of the philosophical and the political implications. We're going to talk about the economic implications of a decision such as this by the Brazilian legislature and the government.

This is the brink of stealing American assets, many of which we pride ourselves on as leading in the pharmaceutical industry and the fact that we're providing these industries to other countries around the world. And under the TRIPPS agreement, which was agreed upon by many of these world countries, Brazil could now declare – based on what they interpret as an emergency clause necessary for compulsory licensing to occur for these AIDS products. Unfortunately a national emergency component of this is incorrect on the grounds that if they're going to declare a national emergency, there's no timeline, there's no parameters set thus far as to what the implications are and what the importance of them making this choice in this regard.

The TRIPPS agreement in the emergency clause for compulsory licensing was set forth and was meant for emergencies in only developing countries. Currently Brazil is not even dedicated to the fact that they are a developing country, which, by the numbers, they actually are not. They claim the world status when convenient. They have the 10th-largest economy in the world. GDP is \$1.3 trillion. It's larger than that of Russia, Canada, Mexico, and can have the accolade of the fourth-largest space program in the world. This is a country that only dedicates 7.9 percent of their GDP towards healthcare. It's very interesting, the facts that those are the numbers that we know to be true in this regard and yet they're claiming developing country status as the necessary reasons for compulsory licensing in this regard.

Despite these major global economic forces, Brazil is demanding from our companies the same prices on medicine offered to poverty-stricken countries such as Rwanda and Zimbabwe – Zambia, I'm sorry. The unfortunate part in that regard is our drug companies in many of these same instances have actually already reduced the cost of these drugs to make it affordable, to put them at basically cost for these countries to provide these to their citizens, and they're actually asking these companies to lower that even further on grounds that have not been proven yet. When you look at the AIDS infection rate, it's .6 percent. Now, no one's, again, addressing the point that AIDS isn't (?) a critical subject, that the drugs should be provided that are necessary, but on par with the rest of the countries around the world. We obviously – and some of my colleagues

have already addressed this – some of the reasoning being is that they’re going to take these products and make generic drugs, being able to create their own pharmaceutical market comparable in their minds compared to that of the United States.

As we look through, this has major implications on free trade agreements, as we have major discussions on the Hill currently on CAFTA, the ongoing discussions in the past from articles such as Thailand and other U.S. agreements, and bilateral agreements. This would have huge implications on the IP components of those, for fear that countries would feel as though they could just circumvent those agreements and intellectual property would just be something on the wayside.

So looking at it in those comparisons and looking at the implications on U.S. industry and the U.S. copyright industry, estimates of losses in Brazil along, just on copyrights components, not on patents, is over \$931 million in 2004, making Brazil the Western Hemisphere’s most offender of IP rights. Brazil’s record on IP rights abuses, as Nancie had pointed out before, has landed the country on the USTR special 301 list for – priority watch list for IP. And the language stated from the priority watch list is very clear – quote – “the most egregious acts, policies or practices, or whose acts, policies or practices have the greatest adverse impact – actual or potential – on relevant U.S. products and are not engaged in good-faith negotiations to address these problems,” which makes it very clear that the violations are ongoing and current with the discussions we have before you today.

So in closing, the implications on not only the U.S. economy – which, as many people can point out, this is – the U.S. workforce – 10 percent of the U.S. workforce is dedicated towards intellectual property, be it in components of content, patent rights and the sort; be it the software industry, pharmaceuticals, entertainment. This accounts for 15 percent of the U.S. GDP, the highest of industries in the country. So the implications on the U.S. workforce – job losses and the economics of it – are very broad and very large, and we have to look at it for those potentials and also for the threat to IP that Brazil is making in this case.

So, thank you.

MR. KOGAN: Thank you very much for a very nice presentation.

I would also like to introduce next Mr. Jerry Norris, senior fellow, the Hudson Institute.

JERRY NORRIS: Thank you, and thank you for coming in this morning.

My involvement with Brazil started when I worked for the Harvard Medical School and I spent a great deal of time working in Sao Paulo between 1997 and the year 2000. So that made me – when I heard about Brazil declaring, or moving to declare a medical emergency, I became interested in what was behind it.

As was just mentioned by my colleague, it's the 10th-largest economy in the world, and if you look at the gross national product, at over \$1 trillion and over 8 percent of that being spent on national health activities, and according to the Associated Press, last year they spent \$180 million on AIDS. That works out to be 0.02 percent of the cost from their total expenditures. So that can't be the reason for the emergency. They certainly spend much more on cancer, much more on cardiovascular diseases, much more on diabetes and much more on a great many other diseases than they do on AIDS.

So what is the real issue, and why in particular are they targeting various companies like Abbott?

From the clinical AIDS treatment experience in the United States and in Europe, there is one certainty, and that is that in time, drug resistance will set in. According to the World Bank, in the United States we've been treating AIDS patients since 1988, and 26 percent of those patients are now what we call drug resistant. That means that they have to move from the first-line therapy that they were put on and put into a second-line therapy. That therapy is much more expensive, but not only for the drug itself. It's much more expensive because it requires specialists in terms of medical care and it often requires hospitalization. So it's the medical infrastructure component that is more expensive than the drug itself.

Now, there are limited options when you move to the second-line therapy, and one of them is manufactured by Abbott Laboratories here in the USA. And the only other competitor that is in the Doctors without Borders pricing guide is a company in India that produces the same drug as a copy but at four times the expense. It's a very complicated drug to produce. So Abbott sells it to the U.N. Accelerated Access program for \$500 per patient per year, and the Indian company sells it for \$2,130. But since the Indian company has already broken the patent to produce this drug – and it's a copy drug of unproven quality, safety and efficacy – it's not competitive to the Abbott product. So we don't have a health emergency as much as we have a commercial opportunity because what the United States and Europe have gone through on drug resistance, what Brazil is now going through on drug resistance, Africa and Asia is going to be right behind it, and they're going to need this second-line therapy. So if Brazil can declare the emergency, expropriate the product from Abbott, it will have a competitive advantage in global markets with this drug.

Now, even at zero price, even if Abbott donated the drug, Brazil still cannot afford the medical care and treatment that's required for patients. So the price of the drug is marginal to the issue. But if Brazil succeeds in declaring a medical emergency and succeeds in breaking the patent, it's only the issue that will open the door to cancer drugs, which account for more mortality in Brazil than AIDS, for cardiovascular diseases, which accounts for more mortality in Brazil than AIDS, AIDS, which accounts for more mortality in Brazil than AIDS. So that's the real issue; it's not AIDS. AIDS, it's popular because everyone is talking about it today, but the real issue is the commercial market for non-communicable diseases.

Thank you very much.

MR. KOGAN: Thank you, Dr. Norris, for your excellent presentation.

Before we open this up to Q&A I'd like to make a statement regarding the broader trade policy issues that are involved here on behalf of the ITSSD, and how Brazil is really drawing more and more industries into their economic realm rather than address the health issues which they claim to exist. Obviously this has something to do with – Dr. Pachovski had alluded to the agricultural subsidy issue in trade, in cotton, and there is an issue regarding how to use negotiations as to a settlement on a prior WTO panel case as leverage to insure a result that is favorable to you. There are broader trade issues here at stake and they're being couched in health terms and public sympathies are being played upon for really economic motives.

And these are the things that we would like to leave you with as notions in your mind that there are invaluable intellectual property rights at stake, that there are really economic issues here at play – there's a much bigger game out there – and that the trade rules, painstakingly negotiated at the Uruguay round and subsequent thereto as part of the Doha, are being trampled on, and that these things need to be addressed.

I wanted to thank all of the panelists here convened today for an excellent presentation in each of the different dimensions of the problem that they have addressed. And I'd like to now open up the floor for Q&A.

Yes?

Q: Mike Palmedo, Consumer Project on Technology. I want to talk about how Brazil is not having a health emergency, which I don't know where you draw the line, but that's only one thing that the TRIPPS – there's only one reason for them to issue a compulsory license – if they decide to issue a compulsory license on the grounds of government use or excessive pricing, or many of the other things. The U.S. has used compulsory licenses for totally un-health-related things. We don't have to prove any sort of emergency.

MR. KOGAN: May I ask your name please?

Q: Mike Palmedo.

MR. KOGAN: From –

Q: Consumer Project on Technology.

MR. KOGAN: And who are you directing your question to?

Q: I guess Mr. Pachovski.

MR. KOGAN: Okay.

MR. PACHOVSKI: The issue here is not compulsory licensing. We would accept compulsory licensing if it is done under the proper procedure. The issue is that Brazil, by taking a domestic legislation, adopting our rule, is proclaiming a vast variety of drugs not specified as non-patentable. They do not follow our procedure. They do not accept what they agreed to previously because if it is compulsory licensing, the patent states the compulsory licensing is limited. It always shows who the patent holder is. There is a debate, a discussion about some kind of compensation about compulsory licensing, and there is always time limit, there is quantity that it has established, there is a process of labor link, how you do it, and so on and so forth.

Those guys, with one move, they are wiping out the issue of patents. They are saying those drugs are non-patentable, because this is the first level in the legislative process. The rule passed unanimously, surprisingly, the lower house of their parliament; it moves up. But with a move, they're creating the basis for state-sponsored piracy. This is like in the Caribbean where the pirates from different countries were taking all the ships and they were not punished in their countries because they were bringing wealth to their countries. They were paying taxes as their industry – pharmaceutical industry will do by stealing those patents. So the issue is not compulsory licensing.

About the emergency, it is a very interesting question. Even if you have one patent, you may proclaim a national emergency, which is strange. There are no rules about what constitutes a national emergency in the international trade war now. It is kind of wide-open for future discussion on this. Is there a threshold when you can proclaim? But still it is good to proclaim national emergency to explain what the situation is to their own population to mobilize the political forces, the economic resources, the cultural mindset and stuff like that, to address the issue. The United States of America offered Brazil \$40 million immediately, deliverable, for free assistance to treat AIDS, with a string attached: that Brazil will change its policy toward prostitution and other prevention issues. Brazil called this – (unintelligible) – fundamentals.

So they don't want to discuss any issue of AIDS and prevention. They're building the ground for their pharmaceutical industry and proclaiming that those drugs are not patentable.

So I would accept and discuss what is compulsory licensing on specific drugs, but this is not the issue here.

MS. MARZULLA: I'd like to add one thing if I may, and it's hard to add to such an excellent response, but I thought I detected one additional point in your question, and if I did, I'd like to encourage you to pursue it, because if I heard you say correctly that you thought the United States itself was perhaps not protecting intellectual property rights as vigorously as it should, then by all means everyone, every country has an obligation to respect and protect intellectual property rights, and I don't think anyone is immune from scrutiny.

And so if that was one component of your question, I think it's a valid point, and I think that we should follow up on that point as well.

MR. KOGAN: Any other questions?

MR. NORRIS: I wonder if I could follow up with Mr. Palmedo. If you could tell us – I wasn't aware that the U.S. has ever issued a compulsory license.

Q: All the time for antitrust events, actually like with TRIPPS. In the article about compulsory licensing it says, in the event that you issue compulsory licenses for anti-trust violations, you can even waive prior negotiation of payment of royalty. So like the Microsoft case that they were forced by the government to license out a bunch of their software patents – I brought a couple of examples with me – tow truck parts. I don't think it's a matter that they're not protecting IP as strongly as they should, but like compulsory licensing provisions are part of just about everybody's patent laws. They're not these crazy things that were invented in 1996 with the creation of the World Trade Center – I mean, the World Trade Organization, which is part of patent law.

MR. COX: Well, I guess – can I respond just really briefly? I guess – I mean, I think there are objections to compulsory licensing regimes as well, but accepting for a minute the idea that you do need some sort of compulsory licensing regime, the huge difference here between what Brazil is doing and a compulsory licensing regime is that with compulsory licensing, there is still some limits, and you still retain the title to that intellectual property and you have some control over its use, and you probably get some payment as well under most of them.

But what Brazil is doing is saying, look, we're going to end the patents, we're going to break the patents, and at that point Abbott Labs or Gilead or Merck have no control over the billions of dollars that they've put into their research and development, and it basically takes away the entire incentive to produce new drugs.

MR. KOGAN: Okay, any additional questions? Please don't feel shy. Okay, well, unless any of the panelists have anything further to add on the subject matter, I guess we will – yes?

MR. NORRIS: What is the position of the U.S. government?

MR. KOGAN: Is there anyone here from the U.S. government this morning – at least that want to admit that they are? (Laughter.)

Not speaking on behalf of the U.S. government, I think that they're aware of all of the issues that we've discussed this morning. The question I think that they're looking for is a well-reasoned, prudent approach to dealing with this without escalating the problem into a global trade war. And what they are, I believe, looking to do is to get intelligent people in the room to speak to them about these various issues and come up

with some type of roadmap. And I think that each of us here would welcome that invitation to speak to various of the government agencies, including USTR.

MS. MAZULLA: If I could add one comment – I've had a couple of discussions with trade representative folks, and I think that – to echo what was said just a moment ago – certainly they're fully aware of what is occurring, and they are actively working behind the scenes. Obviously we don't know everything they're doing, but by the same token, I think that they are looking to you folks, to the media, to report what us thinkers and lawyers and economists have to say about this issue, because I think they are – I mean, they really are in a very tough situation because they have a limited number of tools they can use to solve this problem – I mean, short of sanctions. And of course once sanctions are imposed, where do they go from there?

So I think that putting our heads together and working together on this problem I think is very useful to those people, and I know for a fact that they've told me that they want our input. So I think that's why this morning's session is so important.

MR. KOGAN: Well, thank you again for attending this press conference, and we appreciate any suggestions or comments that you may have. Have a good day.

(END)