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I actually intend in my own discussions to address a narrower issue than the T.R.I.P.S. agreement, but having heard the two previous speakers, I think before I get into my topic of interest, I would first like to just take the opportunity to make some observations about the two previous presentations. Actually, the need to make these observations probably is not that great since at the end of Professor Thomas' remarks and also in Peter Fowler's remarks you heard the answers to some of the questions that were given by Professor Damas, but I want to emphasize my view on a couple of them.

First of all, with regard to the T.R.I.P.S. Agreement¹, the T.R.I.P.S. Agreement was an agreement that was negotiated on the basis of *quid pro quos* among states. Each state gave something and got something. Developing countries and developed countries each had parochial issues, parochial trade, and industrial concerns of interest to them that were important to them in the Uruguay round.² In some cases that was a protectionist agenda, in some cases that was an export-oriented

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¹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, Annex IC, 33 I.L.M. 81 [hereinafter TRIPS] (establishing multilateral agreement creating minimum protection standards for protecting various forms of intellectual property among nations).

² See Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Dec. 15, 1993, 33 I.L.M. 1 (establishing the World Trade Organization (WTO) in the last round of GATT and also creating treaties covering services, intellectual property rights and investment matters).

agenda where they wanted access to other markets. The WTO agreement³ is about market access fundamentally and that is one of the reasons that I think the T.R.I.P.S. Agreement could have come about in the first place. We have long had the World Intellectual Property Organization,⁴ and as Professor Thomas pointed out, the intellectual property agreements are some of the oldest international law that there is. We, for quite a few years, have discussed agenda items like compulsory licensing or geographic indications in the context of amendments to the Paris Convention⁵ or the Berne Convention,⁶ but it was very, very difficult to tackle difficult issues like these because the context in which WIPO treaties are negotiated is basically just an open forum. A lot like this room with 160 different countries sitting here and everybody putting forth their own ideas, and there is not any glue; there is not really any pressure that causes them or forces them to come together upon something. As a result, a number of very significant international agreements like the Rome Convention,⁷ never included key players like the United States. As a result, only some countries adhere to the Rome Convention and recognize the neighboring intellectual property rights therein included. Similarly, there are treaties that the United States has proposed that other countries have never really signed up to. So, even where you can get agreement among negotiating countries in principle, it is really difficult to build a treaty unless a country has some very compelling reason to adhere to the agreement and to disregard what almost in every case, whether it is this country or any other, are going to be very significant domestic interests they are not going to want in the agreement. The underlying message here about the T.R.I.P.S.

³ See Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 [hereinafter WTO agreement] (creating World Trade Organization).

⁴ See The World Intellectual Property Organization, at <http://www.wipo.org>. (last visited Apr. 12, 2003).

⁵ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583 (last revised July 14, 1967) [hereinafter Paris Convention] (creating WIPO and enacting regulations promoting industrial property).

⁶ Berne Convention for Protection of Literary and Artistic Works, Sept. 9, 1886, 282 U.S.T. 1583 [hereinafter Berne Convention] (establishing multilateral treaty composes of nations "for the protection of the rights of authors in their literary and artistic works").

⁷ See Luca G. Radicati Di Brozolo, *International Payments and Conflicts of Laws*, 48 AM. J. COMP. L. 307, 319-322, (2002) (detailing the effects of the Rome Convention on international transactions).

Agreement is that one has to view it in the WTO context. The many agreements concluded under the WTO framework brought many benefits to developing countries, particularly market access. The next time you are shopping at the mall, walk into any apparel store and look on the tag on where the product was made, I think nine times out of ten today you will find that it was not made in the United States and it was not probably made in some other developed country: it was made in a developing country. Back when the Uruguay Round was first getting underway that was not necessarily the case. Clearly participation in the Uruguay Round brought developing countries greater access to developed country markets for their products. That was the principle trade-off and in return we had to get something, and what we got in T.R.I.P.S. was recognition of the value of the intangibles that are the heart of a modern post-industrial economy.

The United States has not even remotely recognized the benefits of T.R.I.P.S. yet, and I also want to point out that T.R.I.P.S. by no means is restricted to patents. Probably the greatest beneficiaries by far of the T.R.I.P.S. Agreement are the information industries. The computer software industry, Hollywood, the sound recording industry and so on, which have used T.R.I.P.S. to capture markets which were previously dominated by piracy.⁸ I should add TRIPS has been applied to protect United States interests in developed countries like Italy where we have reduced piracy rates for computer software for example, by using the principles of the T.R.I.P.S. Agreement.⁹

Now before I get again into my talk, I want to make one other observation concerning the AIDS issue in Africa because it is incredibly interesting to me and because the debate greatly frustrates me.

I think AIDS activists have done a huge disservice to the problem of providing relief to people in the developing world by

⁸ See Nuno Pires De Carvalho, *International and Comparative Law Issues: Requiring the Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution*, 2 WASH. U.J.L. & POL'Y 371, 375-400 (2000) (detailing the strengths and weaknesses of the TRIPS Agreement).

⁹ See also Marian Nash, *Contemporary Practice of the United States Relating To International Law*, 92 AMER.J.INT'L L. 44, 56 (1998) (stating that the TRIPS Agreement does protect computer software as literary works).

directing a disproportionate focus on the patent issue. My organization, IIPi,¹⁰ has been extensively involved in this issue and we have two documents worth viewing on the matter. You will be referred to them if you look at our website, which is *www.iipi.org*. The first was a study in 2000, which is also available on the website of the WIPO, *www.wipo.int*, where we actually looked at the patent status of AIDS drugs in African countries and found that by and large these pharmaceuticals had never even been patented in most African countries.¹¹ That research was updated in an article by my South African colleague, Lee Gillespie-White, at IIPi, and Amir Attaran of Harvard University, in the *Journal of the American Medical Association* in October 2001.¹² Both of these studies really point out that the problem is not patents in most cases.¹³ The problem simply is that there is a market breakdown.¹⁴ The fact is that AIDS drugs under any scenario cost money and that the infrastructure to deliver them to patients cost money, and that in many of these countries the economic foundation to sustain these costs simply does not exist.

Now Brazil is a country that has been much in the news as a successful developing country in dealing with the issue of AIDS.¹⁵ I would first like to point out that Brazil is a pretty wealthy developing country. I think it has about an \$8,000 a year per capita income, maybe \$8,900 now.¹⁶ It also has a small AIDS

¹⁰ See International Intellectual Property Institute, at <http://www.iipi.org> (last visited Apr. 12, 2003) (detailing the operations of the organization).

¹¹ See World Intellectual Property Organization, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, at <http://www.wipo.int/news/en> (last visited Feb. 21, 2003) (discussing IIPi's HIV/AIDS study and findings).

¹² See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JOURNAL OF AM. MED. ASS'N* 1803, Oct. 17, 2001, available at <http://jama.ama-assn.org/issues/v286n15/full/jsc10222.html> (last visited Feb. 21, 2003) (questioning whether patents restrict access to AIDS treatment in Africa).

¹³ *Id.* (stating "patents generally do not appear to be a substantial barrier to antiretroviral treatment access in Africa today").

¹⁴ *Id.* (finding that "the extreme dearth, rather than the patents, is the most to blame for the lack of antiretroviral treatment in Africa").

¹⁵ See Larry Rother, *Departing President Leaves a Stable Brazil*, *N.Y. TIMES*, Dec. 29, 2002, at 1-10 (noting that AIDS-related deaths in Brazil had been reduced by two-thirds).

¹⁶ See e.g., The World Bank Group, *Country Classifications*, available at <http://www.worldbank.org/data/countryclass/classgroups.htm> (last visited Apr. 12, 2003) (labeling Brazil as an upper middle income economy).

population of about 100,000.¹⁷ But the Brazil program still costs \$4,000 a year for each of those 100,000 people.¹⁸ So that is equals an enormous cost if you were to translate that into 30,000,000 people or more in Africa that are affected by AIDS. You can see that the magnitude of those costs simply is unsustainable given the economy of Africa, even under the most liberal intellectual property regime or even the use of generic products. Now one of the things that really inflames me more than anything else about AIDS activists is when they talk about the issue of parallel importation as a solution to the problem and when they oppose national exhaustion of patent rights in the AIDS crisis.¹⁹ Nothing could be worse for dealing with the AIDS problem. If you had assumed the principle of international exhaustion, that is you can shop anywhere in the world that you want and look for the cheapest price for AIDS drugs, do you think that South Africa, if they gobbled every single product on the market would even come close to being able to satisfy their domestic need? Of course they would not. In fact, the issue should be looked at from the opposite point of view. What has to happen is that national markets have to be segregated out so that prices can be established that fit those markets. You are never, ever going to solve the African problem at \$10,000 per capita. Drugs are going to have to be vastly cheaper, and so what is going to have to happen is that a fence is going to have to be put around certain countries. The issue then is less about are they going to get cheaper drugs elsewhere, but are the cheap drugs which are provided to them going to be kept there for their use or whether we'll find them on the streets of New York in a black market facilitated by gray market importation.

So what it really boils down to is the issue of money. I was a loyal member of the Clinton Administration and I am very, very proud of the work that we did, but I have to say one thing that I am still unsettled about is the administration's approach to the

¹⁷ See Patrice M. Jones, *Brazil's free AIDS-drug Program Slashes Cases, Earns Global Interest*, CHIC. TRIB., Dec. 24, 2000 (noting that only one percent of Brazil's population is infected with HIV/AIDS).

¹⁸ *Id.* (stating that Brazil spends approximately \$4,500 a year on each AIDS-infected individual).

¹⁹ See John A. Harrelson, *TRIPS, Pharmaceutical Patents and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175 (2001) (outlining the arguments for national exhaustion of patent rights and parallel importation).

AIDS problem. Professor Thomas mentioned the speech that Vice President Gore gave at the United Nations²⁰ and I remember being in the Vice President's office shortly after he had come back from South Africa and had an awareness of the crises in Africa. At the time I wrote a paper about the crises and sent it to his domestic policy advisor. The paper then got sent to the National Security Shop and I think it was put in a file.

The paper really focused on what the real problem is: a question of money. The Clinton Administration's budget for foreign assistance regarding the HIV disease was \$250 million globally.²¹ Now \$250 million is not even in the ballpark for providing any kind of real drug treatment to millions and millions of people in Africa or elsewhere. In fact, it wasn't even adequate really to support education programs or abstinence programs or whatever else, condom sales, etc. This is an administration that spent \$12 billion on the war in Kosovo²² to deal with the concerns of a half-million press people in Kosovo, but it could not spend any more than \$250 million on AIDS. And that is where the problem lies. Secretary General of the United Nations, Kofi Annan, said we had to have at least a \$10-billion fund, and countries like the United States are going to have to put up at least \$3 billion.²³ I think the Bush Administration's proposal this year is about \$300 million.²⁴ Now initially I thought the Bush people might be actually making some progress there. Tommy Thompson's shop was really looking into this and I thought there was a real possibility frankly that the Bush people might finally realize we needed more money. Frankly, after September 11th this item has really moved down on the agenda.

²⁰ See CNN, *Gore to Announce Major Initiative on AIDS in Africa: Vice President to Unveil Plans at United Nations*, available at <http://www.cnn.com/2000/WORLD/africa/01/09/un.africa.aids.01.htm> (last visited Feb. 21, 2003) (stating that Vice President Al Gore would announce a major policy initiative towards AIDS in Africa).

²¹ See *AIDS Council Criticizes Clinton's Follow-Through*, WASH. POST, Dec. 20, 1998, at A27 (noting that President Clinton's AIDS advisory council criticized budget cuts in AIDS research).

²² See *Military Construction*, WASH. POST, May 21, 2000, at M13 (noting that \$4.1 billion had been earmarked for operations in Kosovo in the year 2000).

²³ See Paul Blustein, *Bush to Announce Three-Year Spending Initiative \$500 Million Set for Global Push to Fight Transmission to Infants*, WASH. POST, June 19, 2002, at A03 (stating Kofi Annan's desire for \$10 billion dollar a year international funding for the prevention of AIDS).

²⁴ *Id.* (outlining the Bush administration's budget proposal for AIDS prevention programs).

The blame is not only in Washington and I think Professor Thomas also pointed out the blame is also in capitals of many of these affected countries where there is a real denial on the part of the leadership that they have a problem at all. Heads of State are coming into Washington day and night practically from all parts of the world to visit the President. Rarely when developing country heads of state or heads of government come to Washington do they ever raise the issue of assistance to their countries on the AIDS question. And one of the leading examples of that is South Africa where the Chief of State has denied that HIV even causes AIDS, as Professor Thomas pointed out.²⁵ I have been in South Africa twice in the last six months, and interestingly that is a very unpopular position, and what has happened now is that provincial governments in South Africa are recognizing there is a problem and they are beginning to provide anti-retroviral drugs to patients in the public health system, and pharmaceutical companies are providing those products at discounted prices.

So to try to suggest that the big bad pharmaceutical companies are the source of the problem is really doing a disservice to the millions of people who desperately need these therapies.

With all that said, I now have only about five minutes left for my real talk, which is thankfully written up in the materials. After I left the Clinton Administration I felt very much obligated to try to do something about helping developing countries actually be able to use the benefits of TRIPS and the benefits of intellectual property rights for their own development. To me it is self-evident that the wealth of the world today and in the future is in creations of the human mind. It is not in sweatshops and it is not in increasingly lowly valued commodities. There is not a commodity product in the world whose absolute value has risen in the last twelve years across the board; the commodities that developing countries have to sell are not even remotely capable of sustaining economic growth and meeting the needs of their population. And all you have to do I think is go down to the maquiladora factories of Mexico where a lot of manufacturing is going on and ask if you would like American workers to live and

²⁵ See *Aids in South Africa*, THE TIMES (London), Jan. 18, 2003, at 25 (noting South Africa's Chief of State denied the causal link between HIV and AIDS).

work in those conditions. That is not what we call the road to becoming a developed OECD²⁶ member country.

So these countries have to begin making greater use of modern institutional and legal tools to channel their intellectual resources into productive industries that can reshape their economy so that they can compete in the global environment. Developing countries certainly are not lacking in the brainpower to build the knowledge-based industries at the forefront of economic growth. Silicon Valley would be hard pressed to function today without bringing in software engineers from developing countries. And in fact one of the major legislative priorities of the business software alliance, in the last congress was H1B Visa authority, so that they could meet their labor shortages by bringing in from all over the world scientists and engineers, which we weren't producing in sufficient numbers here in the United States.²⁷

So clearly the talent exists, but just as clearly that talent is not being exploited back home. Instead, many countries are content with their children working in sweatshops and their PhD scientists living in Seattle. This is a problem that needs to be addressed.

I have some statistics that I want and I wish I had time to do a PowerPoint and put them up on the screen. But I think these statistics tell the whole story and what the real nature of the problem is. Here it would be a little more complicated situation talking about copyrights, but let's talk about patents and the law of technology, and clearly computer software, computer inventions, biotech inventions, etc., are all patentable subject matter.

There is one principle source of data concerning who uses the global patent system. The World Intellectual Property Organization publishes, and it is available on its website, an annual report of patent statistics.²⁸ This report gives patent

²⁶ See Ben Wattenberg, *Don't Wobble on Immigration*, WASH. POST, Mar. 30, 2002, at A17 (noting that Mexico is a member of the OECD).

²⁷ Donald W. Smith, *Defense of Export Control Enforcement Actions*, in *COPING WITH U.S. EXPORT CONTROLS 2002*, at 807, 1159-62 (PLI Com. L. & Practice Course, Handbook Series No.844, 2002) (discussing high amount of H1 B visas for foreigners to work in "advanced electronics").

²⁸ World Trade Organization, *WIPO Industrial Property Statistics*, available at <http://www.wipo.org/ipstats/en/publications/b/index.htm>. (last visited Feb. 21, 2003) (allowing searches of all WIPO statistics since 1994).

filings in every patent office, for every country in the world, and gives the number of people who are granted patents, and it identifies which of those are foreign nationals and which are domestic applicants. Those are patent applications filed in national offices, and then the World Intellectual Property Organization also administers a multi-national filing system called a patent cooperation treaty in which you can in one single filing apply for patents in many countries of the world. So if I am IBM and I am filing an application at the USPTO I can say I also want protection in Germany, Switzerland, Sweden, South Africa, UK, Brazil, and so on. If you look at the statistics, the statistics for use of the PCT are that 95.5% of all PCT applications come from nationals of OECD member countries.²⁹ And if you include China and Israel, into the mix it goes up to over 99%.³⁰ So roughly 1% of the world's patents come from everywhere else, from India, from Brazil, from Argentina, from South Africa, from countries many of which have a significant technological capability – Malaysia, Singapore, etc.

Now what does that mean for the T.R.I.P.S. Agreement? What does that mean for global development? I think it means that the T.R.I.P.S. Agreement is unsustainable unless we start to have more equity in its actual use. And this pushback that you are seeing, which may or may not be justified in the health area, I think is largely because the T.R.I.P.S. Agreement remains eight years after its inception an agreement in which 99% of its use, at least in the patent system, comes from a handful of developed countries. That problem must be addressed, and there are two issues that need to be addressed. One, which since my time is almost up I won't go into it, which is somewhat complicated, but it is that these countries lack by and large the means to effectively examine patents, and so that problem has to be dealt with. For example, in South Africa, there isn't an examination system, but a *de facto* registration system.³¹ So if I am a

²⁹ WIPO Industrial Property Statistics Publication B 2000, Part I, Table I, Patent applications filed and patents granted, available at <http://www.wipo.int/ipstats/en/publications/b/2000/pdf/pattab1.pdf> (last visited April 11, 2003).

³⁰ *Id.*

³¹ See Explanation of Terminology in the Proposal "Toward the Development of APEC" Japan Federation of Economic Organizations, available at <http://www.keidanren.or.jp/english/policy/pol1065/term.html>. (last visited Feb. 21, 2003) (discussing countries that do undertake substantive examinations and noting that South

pharmaceutical company or a biotech company and I file a patent in South Africa, in effect I am just filing it and I have all of the very extensive property rights that I would have in the United States, but nobody has ever taken a look at my claims to really determine whether I should have those rights in all of those claims. That never happens in the United States.

Then of much greater importance, we need to help encourage these countries to file patent applications. I did some work in Jamaica two years ago and initially I was thinking that there would be very little relevance of a patent system in Jamaica. But I found that in the year preceding my visit that the University of the West Indies, a technological university in Jamaica, had been approached by foreign entities on licensing technology, which they had under development. Had the Jamaicans patented these inventions, they would not have been at a distinct disadvantage when they negotiated an agreement.

But it doesn't do any good to file a patent application just in Jamaica. Jamaicans need to build the capacity to file patent applications in the United States and in the European Patent Office; a very expensive process way beyond their means.³²

I was in South Africa. South Africa does file more patents than some other countries. The University of Cape Town, one of the leading research institutions in the country has not a single patent filing in the United States, and yet they have research that may lead to very significant advances, including significant advances in dealing with local health and agricultural problems. The lack of patent filing by developing country institutions in developed counties is a problem that has to be addressed and it will only be addressed if the world community kicks in and basically creates a funding mechanism for the disadvantaged to get into the system. International aid groups like The World Bank have yet to focus on the issue. They are providing all kinds of infrastructure like building sewers and roads and out-of-date steel mills. They should be looking at providing countries the type of infrastructure necessary for their citizens to export the

Africa does not).

³² See Jamaica: Marketing U.S. Product and Services, *available at* <http://www.tradeport.org/ts/countries/jamaica/market.html>. (last visited Feb. 21, 2003) (discussing the lack of enforcement of IP laws in Jamaica due to overburdened courts and police).

products of their mind, rather than export their bodies to Silicon Valley. And until we start to address that problem which seems to be off the radar screen of policymakers, I think we are going to have a very unbalanced use of the T.R.I.P.S. Agreement, particularly in the patent area and it will remain unstable for the duration of that unbalance.