

PANEL I: AIDS Drugs and the Developing World: The Role of Patents in the Access of Medicines

Facilitator: Mark Warner^{*}
Panelists: Amir Attaran^{**}
Susan Finston^{***}
James Love^{****}
Robert L. Mallett^{*****}
Coenraad Visser^{*****}

MR. WARNER: The *Fordham IPLJ's* Symposium Editor Margaret Ross has asked me to facilitate this panel. I was originally going to be just a speaker, and I think now that I know what is involved with being a facilitator, I might have preferred just being a speaker. I think you are in store for a very good and lively panel today. I think we have a tremendous range of opinions to be expressed. What I thought I would do, just to start out quickly, is introduce my fellow panelists, then make some introductory remarks, and then let everyone speak for about ten minutes each, and then have a question-and-answer period and maybe a chance for some

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dialogue among the panelists. I think some of you who have come earlier have seen the dialogue began a bit early as well.

The speakers are: Robert Mallett, a senior executive at Pfizer here in New York, and he has been working on these issues for quite a while. We have Amir Attaran, who told me today he did not want to be called a professor. When Susan Finston came in, she addressed both Robert and me as professors. We used to be, but we are not any more. Amir tells me that he is not a professor, even though he is listed as a professor on the program, and he really did not want you to get the wrong idea, so he wanted me to clarify that he is not a professor. He is at Harvard, though, and he has been working on these issues. You see from the materials and from reading your newspapers, he has just authored a very contentious and important study.

We also have another speaker who is joining us from South Africa who is a professor, and he is Professor Coenraad Visser from South Africa, who has again been working on the issues of intellectual property for a great many years and thinking about these issues. As you know, South Africa has been a major battle zone on this issue for quite some time, so it will be very interesting to hear his remarks.

Susan Finston is with Pharmaceutical Research and Manufacturers of America (hereinafter "PhRMA"), which is the industry trade association for the pharmaceutical industry here in the United States. She works particularly on international issues. She comes from a background at the State Department, one of the lucky ones who found a way to bring public policy into private practice.

Jamie Love is from the Consumer Project on Technology, which is affiliated with Ralph Nader, and has been doing very good work on this. Jamie also did an affidavit in the South African pharmaceutical case, which you have all read about, last April, which was very influential in those proceedings, and has been really a major force in this debate, and we are going to see some of that up on the stage here. So you see we have a very, very good panel here.

I thought what I would do to begin is to make some introductory remarks, as a practicing lawyer who has worked a little bit on these

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issues in private practice and a little bit in my recent stint at the Organization for Economic Cooperation and Development (hereinafter “OECD”) in Paris¹.

It is really interesting. When I was working at the OECD, until last December, I thought that all of the public policy issues that I worked on were really academic. Before I went to the OECD, I was teaching at the University of Baltimore School of Law² and I was an academic, and I thought, “wow, this is all very interesting,” and I thought it was all very abstract. Then I went to the OECD to be an international civil servant and I realized that it got even a little bit more abstract when you try to please twenty-nine Member States and think through policy options for the future.³ And then, when I came to private practice and started working with clients who have real interests in getting their products distributed into the market and having to address very real issues about property rights, about humanitarian values, it became a little less abstract, a little less academic, and a lot more real.

How do you take these public policy ideas into practice, how do you get AIDS drugs or antiviral drugs to the people who need them? We are all working at this, but coming at this from a different direction. You have doctors in the field, nurses in the field, people who work in the health care industry and the care-giving area, who are coming at the issue in a very hands-on way. You have pharmaceutical companies, you have researchers who work in pharmaceutical companies who are researching and collaborating with universities and trying to come up with new ways of understanding the problems and new solutions to the problems. You have businesses who are trying to find ways, you know, if you enter into a pharmaceutical business, you are not, it seems to me, just there to make a profit. There are an awful lot of other profitable industries you can work in if you want to just make money. Obviously, you are there because you are interested in working in that industry at some level. So you have business people who are in an industry that is

¹ The OECD Web site may be accessed at <http://www.oecd.org>.

² The University of Baltimore School of Law Web site may be accessed at <http://law.ubalt.edu>.

³ See information regarding OECD, at <http://www.oecd.org>.

important and who have an objective, which is to bring products to market that are quite useful. And then, you have people in an important constituency, in the Non-Governmental Organizations (hereinafter "NGOs") constituency, who are bringing important issues for testing our understanding and challenging us to think deeper and harder and longer, and that is such an important role.

I am one of those people with a varied experience in life, who thinks that when you bring all of that together, you begin to find credible and creative solutions. And so, panels of this sort are extremely important and part of the process in beginning to address the problem.

What is the problem? Well, the problem I think we are here really to discuss is this tremendous problem of AIDS, and particularly as it is affecting developing countries, particularly in Africa, although we see tremendous growth rates in many, many countries with greater populations now, which promises a time bomb to come.

But before we get lost in some of the debates, it is important to go back to some of the basic statistics, the parade of horrors that can get lost in a discussion of this kind.

You can pick up statistics almost every day. I am using a source from last year, but I think it really does help underscore the importance of this conversation and this debate.

AIDS is now the leading killer in sub-Saharan Africa.⁴ While 200,000 people died as a result of conflicts of war in 1998 in Africa, AIDS killed 2.2 million.⁵ In 1999, 2.6 million worldwide died of AIDS, the highest number in a single year since the beginning of the epidemic.⁶

⁴ See UNAIDS AIDS Epidemic Update, World Health Organization (Dec. 2001) [hereinafter *UNAIDS Epidemic Update*], available at <http://www.unaids.org>.

⁵ See AIDS in Africa: How Many People in Africa are Infected with HIV/AIDS?, AVERT (Mar. 3, 2002), available at <http://www.avert.org/aafrica.htm>.

⁶ See *UNAIDS Epidemic Update*, *supra* note 4.

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The progression of the disease has outpaced all projections. The World Health Organization (hereinafter “WHO”) projected in 1991 that in 1999 there would be 9 million infected individuals and nearly 5 million cumulative deaths.⁷ The reality in 2000 is many times higher, with 36 million infected individuals and 16.3 million cumulative deaths.⁸ Around one-third of those currently living with HIV are between the ages of 15 and 24.⁹

I just wanted to start with some numbers because it is important that we see the backdrop against which we are really trying to address this issue. As I said, people have been working on this issue for a long time. There have been many, many initiatives. We have seen some of the major pharmaceutical companies launch initiatives of their own to come up with antiviral drugs at reduced prices, but not at prices that have pleased everyone.

As a result, the Secretary General last year in 2000 convened a meeting of five or so of the major pharmaceutical and multinationals in the world and as a result came up with something called the Accelerated Access Initiative for AIDS Drugs.¹⁰ This was an initiative that would start with an idea of having a partnership between the public sector, the private sector, and interested members of the NGO community.¹¹ This is a problem that we really cannot defeat unless we throw all our resources at it and try to understand it, and we should work collaboratively and not be in combat.

⁷ See, e.g., The Foundation’s Core Values Challenge Us to Expand Our Global Involvement, San Francisco AIDS Foundation (2001), available at http://www.sfaf.org/aboutsfaf/outreach/april101/commentary_global.html (stating that “the World Health Organization now reports that 36 million people worldwide are living with HIV, which is 50% above its 1991 projection.”).

⁸ See UNAIDS *Epidemic Update*, *supra* note 4.

⁹ *Id.*

¹⁰ See UNAIDS Press Release, New Public/Private Sector Effort Initiated to Accelerate Access to HIV/AIDS Care and Treatment in Developing Countries, May 2000, available at <http://old.healthnet.org/programs/e-drug-hma/e-drug.200005/msg00027.html> (announcing a new dialogue between five pharmaceutical companies and United Nations organizations to explore ways to accelerate and improve the provision of HIV/AIDS-related care and treatment in developing countries).

¹¹ *Id.*

And so, with the Secretary General's initiative, each of these companies came up with a series of commitments, some dealing with pricing, some dealing with teaching, some with research.¹² I would commend to you, for those who are interested in this, to go on the UN Web site where you can see an update, a progress report that was released just a few days ago, which updates the commitments that have been made by the five original companies and now the seven largest pharmaceutical companies.¹³ This is an important step forward. Is it perfect? Probably not, but it is a step forward.

Since we are here in a law school, I want to frame the legal issues that are raised by this, and I will discuss them later on. We have, of course, humanitarian and compassionate values. We see a tremendous crisis, a tremendous problem, and the urge is to solve it. How do we help these people? The instinctive response is to say, "well, give the drugs away." But we know that drugs have to be brought about as a result of research and development. This is the tension that we are still trying to work our way through: How do we create the incentives for companies to make the necessary investments in research and development to develop the drugs that are going to have some hope, some promise, of solving the parade of horrors that I mentioned earlier. And so, that at some level is an economic question, at some level it is an empirical question, and I think we will hear from Amir later on some attempt to evaluate those claims.

But at any rate, it is my view that at some point we are not going to get a complete answer and it is going to be at the end of the day a philosophical question of where you want to situate and balance risk and reward. That is not going to be easy. We are not going to have, I think, a magic bullet that is going to tell us the exact place to balance. But that is just one idea.

We see a conflict between intellectual property law and competition law. We live in a market-based society that places tremendous emphasis on competition, so the first thing people see

¹² *Id.*

¹³ See Accelerating Access to HIV/AIDS Care, Treatment and Support, Nov. 2001, available at http://www.unaids.org/acc_access/AAprogress1101.doc.

when they look at pharmaceutical companies with patents that run for twenty years is, “Aha! That is a monopoly.” Well, is it a monopoly right or is it a patent right? Is it a property right? Is there a difference, should there be a difference, and how are we to evaluate that difference? At any rate, there is an unresolved tension there.

In the Spring Term the Supreme Court declined to grant certiorari in a case involving Xerox and CSU, which presented the interface between antitrust law and IP law in the United States.¹⁴ Just so we have our reality check there, these are issues that remain difficult ones, even without taking in the backdrop of the numbers of people infected with HIV/AIDS. These are difficult issues about where we set the boundary. As we saw last year with the *Microsoft* case, as we saw before with the case involving Kodak, these are very difficult lines to draw, but we try to find a way to draw them.¹⁵ On balance, we come out on the side—even antitrust law comes out on the side—of saying that we have to respect the incentives that are there for people to invest in research and development. But at any rate, it is not by any means a simple debate.

We see another contrast between trade and intellectual property law. We have trade agreements. The great innovation in the Uruguay Round Trade Agreement that began in the mid-1980s and concluded in the early-1990s, was the introduction of intellectual property rules, what we call Trade Related Intellectual Property Rights (hereinafter “TRIPS”), into the World Trade Organization (hereinafter “WTO”), into what was before the General Agreement on Tariffs and Trade (hereinafter “GATT”).¹⁶ That was a major step

¹⁴ C.S.U. v. Xerox Corp., 202 F.R.D. 275 (D. Kan. 2001), *cert denied*, 531 U.S. 1143 (2001).

¹⁵ United States v. Microsoft, 253 F.3d 34 (D.C. Cir. 2001) *cert. denied*, 122 S.Ct. 350 (2001); Image Tech. Services, Inc. v. Eastman Kodak, 125 F.3d 1195 (9th Cir. 1997).

¹⁶ See Agreement on Trade Related Aspects of Intellectual Property, Apr. 15, 1994 [hereinafter *TRIPS*], available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm6_e.htm; see also General Agreement on Tariffs and Trade, 1994 [hereinafter *GATT*], available at <http://www.worldtradelaw.net>; Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1363 (Fed. Cir. 1999), *summary judgment granted, dismissed*, 88 F. Supp. 2d 1288 (N.D. Ala. 2000), *aff'd*, 253 F.3d 695 (Fed. Cir. 2001) (“[T]he owner of proprietary information has no obligation to provide it, whether to a competitor, customer, or supplier. Precedent makes clear that a customer who is dependent on a manufacturer’s supply of a component can not on that ground force the producer to provide it; there must also be an

forward. It basically took the lowest common denominator, if you like, of the rules that were out there and codified them, at least that is my perspective; maybe others disagree.

But that is a step forward. We had in the early days of the WTO an attempt to put intellectual property rights in the WTO agreement, and that failed. So this is really quite an innovation that we achieved in the 1990s. It is not perfect, but we are still testing and we are working our way through it.

There are very, very difficult challenges imposed by trying to balance now these issues that, as I said, are not completely settled under our domestic law, and balance them now in the trade setting with a global institution, a worldwide institution.

I just got my flag to stop talking, and I was just getting interesting. At any rate, let me conclude by just taking thirty seconds to say one thing more. We have this conflict between trade and intellectual property, and we also have the underlying issue of development. Now, let me just say that I was born in a country called Trinidad & Tobago many, many years ago. The first Prime Minister of that country was a man named Eric Williams, a noted academic and scholar who wrote, and kept writing when he was Prime Minister.¹⁷ One of the books he wrote, after about five years as Prime Minister of Trinidad, was entitled *Inward Hunger: The Education of a Prime Minister*.¹⁸ I commend it to any of you who want to read it. Basically, the book explains all of the things he wanted to do when he led an independence movement from Britain in the 1960s, independence, and how difficult it was to accomplish these things as Prime Minister, and he called it “inward hunger.”¹⁹

anticompetitive aspect invoking the Sherman Act.”). The court continued: “In response to Intel’s argument that its proprietary information and pre-release products are subject to copyright and patents, the district court observed that Intel’s intellectual property ‘does not confer upon it a privilege or immunity to violate the antitrust laws.’ That is of course correct. But it is also correct that the antitrust laws do not negate the patentee’s right to exclude others from patent property.” *Id.*

¹⁷ Eric Williams was Prime Minister of Trinidad and Tobago from 1962 to 1981.

¹⁸ See ERIC WILLIAMS, *INWARD HUNGER: THE EDUCATION OF A PRIME MINISTER* (1970).

¹⁹ See generally *id.*

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When we talk about the development priorities of African countries, of building infrastructure, getting the drugs to market, refrigeration, transportation, electricity, communication links—all of these need to be strengthened, and in some cases built, in some cases rebuilt. That is the backdrop of development underpinning this issue of dealing with AIDS, and it is what makes it so crucial and so difficult. Imagine the difficult choices confronted by the leaders of any of these countries when told that they are about to get a multibillion-dollar loan from the World Bank and 90 percent of it has to go to AIDS projects. They are important projects. But just imagine the difficulties of making those choices as a leader of a nation.

We are going to get right into it now. I am going to call on my colleague Robert Mallett from Pfizer, to give us his perspective on some of these issues.

MR. MALLET: Thank you very much, Mark, and good morning to you. I thought I was talking to mostly law students who had not yet become cold lawyers, so I thought I could say “good morning” to you.

First, let me begin by saying that it would be very difficult to listen to the numbers about what is happening on the continent of Africa with respect to AIDS and not be completely and totally moved by it, and feel like there ought to be something that those of us who live in a very developed country can do.

We have landed people on the moon, we are building space shuttles. Surely this country, in concert with many others, can respond to this tragedy of gigantic proportion in a more compassionate and systematic way. And we all look for the silver bullet. We all want it to happen, because we know and believe in our capacity to solve problems.

I became a lawyer, many years ago now, because I believed in the law’s ability to sort out problems. One of the reasons that many of you are in law school and some of you may have become lawyers is for that same or similar reasons. But in our zeal to solve problems we sometimes target the wrong things or we have to develop some

bad arguments to get to the right arguments. That happens. And I think so it is with this issue of access to medicines in Africa, primarily sub-Saharan Africa. We could solve that problem if there were no such things as patents that, some have alleged, have prevented medicines from getting to suffering people dying of AIDS in sub-Saharan Africa.

The first thing I would like to say to you today is that the lack of access to drugs, almost any drugs—not just patented medicines, but medicines off-patent, in Africa and many developing countries, certainly the fifty or sixty poorest countries in the world, is absolutely not about the presence of patents. It is about the prevalence of poverty.

Africa—I do not know how many of you have been there, but I have been there in my work as a Deputy Secretary of the Department of Commerce in the second half of the Clinton Administration.²⁰ Part of my responsibility was trying to develop a commercial strategy in dealing with Africa, and I went several times.

Africa is a vast, resource-rich, beautiful continent of over 700 million people who are some of the world's poorest, desperately poor people.²¹ It is often ravaged by war, by famine, drought, pestilence, corruption. There is a lack of clean water in many parts of Africa, poor sanitation systems, insufficient infrastructure of almost every kind imaginable: communications, transportation, education, technology, finance, and of course, health care.

It is difficult, I believe, for many of us in this room to appreciate the magnitude of the poverty that consumes Africa, and we see poverty mainly through Western eyes. We often say, "Africa is poor," and we make it sound as if we are making some kind of very antiseptic, clinical reference. We know it, but we do not really know what it really means. We have nothing really to compare it to. You cannot imagine. You have not seen this level of poverty. And although seeing is sometimes believing, sometimes our mind's eye

²⁰ Robert Mallett served as the Deputy Secretary of the United States Department of Commerce under President Bill Clinton from 1997 to 2001.

²¹ See Africa Population Statistics, available at <http://www.globalgeografia.com>

can help us to understand what we may mean when we talk about how poor this continent is.

Nigeria is Africa's most populous country, with 107 million people.²² Only 59 percent of those 107 million people have access to safe drinking water.²³ There is one doctor for every 3,707 people.²⁴ Mississippi, our poorest state, has 2.7 million people and one doctor for every 850 residents.²⁵

Botswana, one of the longest-running democracies in Africa, a small country in Africa, about the size of Texas, has 1.6 million people, and one out of every three adults in Botswana is reputed to be HIV-infected.²⁶ It has sixteen general hospitals, one mental health hospital, 200 clinics, 339 doctors, and 3,300 nurses.²⁷

In Tanzania 49 percent of the population has access to clean water, in Madagascar only 16 percent of the population does.²⁸ Twenty-three percent of Mozambicans have adequate sanitation.²⁹ In many

/africa_eng/africa.htm.

²² See Nigeria Population Statistics, available at http://www.globalgeografia.com/africa_eng/nigeria.htm.

²³ See WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation Coverage Estimates 1980-2000, Access to Improved Drinking Water Sources, Nigeria, Sept. 2001, available at <http://www.childinfo.org/eddb/water/africa/africa.htm>.

²⁴ THE STATEMAN'S YEAR BOOK, THE POLITICS, CULTURES, AND ECONOMICS OF THE WORLD 1231 (2002).

²⁵ *Id.* at 1846; see also *Mississippi to License Physician Assistants*, AMERICAN MEDICAL NEWS, Aug. 28, 2000, at 43.

²⁶ See The World Factbook: Botswana, United States Central Intelligence Agency, available at <http://www.cia.gov/cia/publications/factbook/geos/bc.html>.

²⁷ THE STATEMAN'S YEAR BOOK: THE POLITICS, CULTURES AND ECONOMICS OF THE WORLD 321 (2002).

²⁸ See WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation Coverage Estimates 1980-2000, Access to Improved Drinking Water Sources, United Republic of Tanzania, Sept. 2001, available at <http://www.childinfo.org/eddb/water/africa/africa.htm>; see also WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation Coverage Estimates 1980-2000, Access to Improved Drinking Water Sources, Madagascar, Sept. 2001, available at <http://www.childinfo.org/eddb/water/africa/africa.htm>.

²⁹ See WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation Coverage Estimates 1980-2000, Access to Improved Drinking Water Sources, Mozambique, Sept. 2001, available at <http://www.childinfo.org/eddb/water/africa/africa.htm>.

countries in sub-Saharan Africa there are fewer than three doctors per 10,000 people.³⁰

South Africa, the most robust and economically developed of all the African states, has a GDP that is less than that of Los Angeles.³¹ Estimates are that at least 40 percent of its army is HIV-positive, and so is nearly a tenth of its population.³² It spends about \$230 per capita on health care overall.³³

In Uganda, which has the most successful of anti-AIDS programs on the continent, only 38 percent of its population of nearly 22 million has access to clean drinking water.³⁴ It has about 57,000 telephone lines, eighty-one hospitals, 840 doctors, and 2,800 nurses.³⁵ Almost ninety percent of its population lives in rural areas.³⁶

The facts are that most countries in sub-Saharan Africa do not have the current capacity to deliver basic health care services to their

³⁰ *AIDS and Health Care in the Developing World*, PhRMA 2001, available at <http://www.phrma.org>.

³¹ See The World Factbook: South Africa, United States Central Intelligence Agency, available at <http://www.cia.gov/cia/publications/factbook/geos/sf.html> (stating that the GDP of South Africa was \$369 billion in 2000); see also Los Angeles on the Rise: Capital City for the 21st Century, L.A. Rising, The Los Angeles Chamber of Commerce, available at <http://www.lachamber.org/aboutla/rising.html>.

³² See Paul Kirk, *Sixty Percent of Army May be HIV-Positive: Preliminary Testing Reveals that 60-70% of South African Soldiers May be Infected with the HIV/AIDS Virus*, DAILY MAIL & GUARDIAN, Mar. 31, 2000 (stating that the rate of HIV/AIDS infection in the South African National Defence Force may be as high as 60-70%); see also *South Africa AIDS Crisis Worsens*, BBC NEWS, Apr. 19, 2000 (stating that the AIDS epidemic in South Africa has reached alarming new levels, with 10% of the population now infected with HIV).

³³ *World Development Indicators 2001: Health Expenditure, Services and Use*, available at <http://www.theworldbank.org>.

³⁴ See WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation Coverage Estimates 1980-2000, Access to Improved Drinking Water Sources, Republic of Uganda, Sept. 2001, available at <http://www.childinfo.org/eddb/water/africa/africa.htm>.

³⁵ THE STATEMAN'S YEAR BOOK: THE POLITICS, CULTURES AND ECONOMIES OF THE WORLD 1591 (2002).

³⁶ See Background Information on Uganda, Developing National Information and Communications Infrastructure (NICI) Policies, Plans and Strategies: The 'Why' and 'How', NICI in Africa, 1999, available at <http://www.bellanet.org/partners/aisi/nici/uganda/uganab.htm> (last visited Mar. 8, 2002) (stating that 88% of the population of Uganda live in rural areas).

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populations. They lack basic roads. They have very little water supply and inadequate sanitation systems, which as we well know, are the foundation of good health care systems. They have deeply entrenched cultural norms and social stigmas, and the lack of education that prevents the treatment of AIDS and lack of adequate public funding for health care. Many of them are simply at the mercy of governments who lack the means of financing adequate investment in health care.

The World Bank says that for every \$100 spent by African governments on drugs, only \$12 worth of medicine reaches patients.³⁷ Their storage and distribution systems are either nonexistent, very poorly managed, and a lot of corruption, resulting in very significant losses of medicine.³⁸

The location of health care facilities is based on political factors or where physicians live, rather than where the neediest patients live. Facilities tend to be concentrated in cities far from rural populations.³⁹ Many doctors and nurses and counselors do not receive adequate training or resources to be able to properly treat HIV patients.⁴⁰ Health workers remain poorly paid, and it is only through personal dedication that they are often able to provide good care under very tough circumstances.

I say all of this simply to create a context for us to talk about these issues. I could go on and on talking about how hard it is for people to get to the doctor. I have seen it. I have been there. I have been in clinics there. The cultural norms and social stigmas are, if you just think about the way we first heard about AIDS, if you can remember, back in the early 1980s, and all of the tremendous social stigmas attached to this disease. But think about it in Africa. It is filled with

³⁷ See Pharmaceutical Research and Manufacturers of America (PhRMA) Backgrounders and Facts: AIDS and Health Care in Africa, available at <http://www.phrma.org/publications/backgrounders/world/aidsinafrica.phtml> (last visited Mar. 8, 2002) (citing World Bank statistic that for every \$100 spent by African governments on drugs, only \$12 of medicines reach patients, and stating that existing networks of health facilities are often physically inaccessible to the population).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

very traditional kinds of collections of people, some in villages, and lots of different tribes and sects. People do not know their HIV status often, and they do not want to know, many of them, because they are afraid of the social stigma that attaches to them.

In KwaZulu Natal, a province in South Africa, a woman was stoned to death simply because she had gotten infected with AIDS through her husband and was trying to launch an education and prevention campaign.⁴¹ She was stoned to death.⁴² People called her sexually active and all kinds of things.⁴³ It was a very, very sad situation.

There is a huge opposition by many clerical leaders to the distribution of condoms in certain parts of Africa, and that has undermined education campaigns and prevention programs. Even in South Africa, the government, after pillorying pharmaceutical companies, suggested that the patents had prevented medicines from getting to the poor, when many, many companies discounted their medicines by 80 percent and 90 percent and provided them at cost.

In the case of Pfizer, my company, we decided we would not enter this debate about what medicines cost because no cost is low enough. Many people on the continent live on less than a dollar a day.⁴⁴ We do not sell an antiretroviral drug (hereinafter "ARV") in South Africa or in any other country outside of the United States. We do, however, have one of the leading drugs, Diflucan, which is the gold standard treatment for opportunistic infections that you get as a result of having AIDS: esophageal candidiasis in your throat, where you

⁴¹ See Jean Dussalt, *The Stigma of AIDS*, United Nations Educational, Scientific, and Cultural Organization, available at http://www.unesco.org/couvier/1999_10/uk/dossier/txt35.htm. (In her village in KwaZulu-Natal, the South African province hit hardest by the AIDS epidemic, Gugu Dlamini was accused by fellow-villagers of having shamed the community by talking publicly about being HIV-positive. After she was beaten by a neighbor who advised her to keep quiet, she went to the police but they were unable to protect her. The next night, her house was attacked and the villagers stoned and beat her to death).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ See, e.g., Global Economic Prospects and the Developing Countries 2001, Prospects for Development, The World Bank Group (2001), available at <http://www.worldbank.org/prospects/gep2001>.

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cannot eat, you cannot swallow; or cryptococcal meningitis that swells your brain up. Diflucan is the drug.

We decided we would give Diflucan away in South Africa and Uganda, and we would give it to any of fifty world's poorest countries anywhere who asked us for it, on the conditions that we must be able to deliver the drug to patients and that the drugs we give in this society to any of these places do not work themselves back into the developed world.⁴⁵ We spent nine months negotiating this agreement with the Government of South Africa to get Diflucan into their clinics, and we got them in.⁴⁶ I cannot tell you how difficult it has been to get patients to come into the public hospitals—and most patients in South Africa go to public hospitals, 80 percent of the people who seek this treatment for this disease.⁴⁷

My time is up now, but I just wanted to paint the picture of how difficult it is. Whatever we have to say about TRIPS and other kinds of things, these issues are hard, and they are issues that we are eternally trying to solve. This is about poverty, it is not about patents.

MR. WARNER: Jamie, we have you coming next.

MR. LOVE: My name is Jamie Love. I work in Washington, D.C. I am told that I have ten minutes, with a panel of six people, and so I am going to be the minority viewpoint here and I am not going to be able to convey very much of my presentation, because I just do not have enough time.

If you really want to believe that patents do not matter in Africa, the drug companies do everything they can, activists are really just some kind of ignorant people who are all worked up emotionally over something that does not make any difference, I probably cannot persuade you otherwise. It depends kind of what you are looking for.

⁴⁵ See Pfizer Press Release: Pfizer Reports Significant Progress on Diflucan Partnership Program, Jul. 5, 2000, available at <http://www.pfizer.com/pfizerinc/about/press/diflucan.html>.

⁴⁶ *Id.*

⁴⁷ See *AIDS Patients Still Awaiting Drugs*, DAILY MAIL & GUARDIAN, Feb. 9, 2001, available at <http://allafrica.com/stories/200102090146.html> (stating that 80% of AIDS patients seeking treatment in South Africa are treated at public hospitals).

If you want to feel better about yourself, you want to feel better about America, people dying is not your fault, there are a lot of reasons that you will hear today that will sort of make you feel that way.

I am going to give you a different picture of what is going on.

[Slide] These are the infection rates in South Africa for pregnant women that were tested last year when they come in, they are pregnant, and they go through these clinics.⁴⁸ These women are going to die if they do not get access to drugs. There are right now about 500,000 people who should be receiving triple therapy in South Africa. There are about 12,000 who get the drugs.⁴⁹

[Slide] This is a little story that is in part of a compulsory licensing brief we are working on that has to do with the impact and the situation with orphans and things like that.⁵⁰ A lot of their primary caregivers are about ten years old now.

It is so bad that there is nothing I can really do. I am not going to zip through a million statistics. But the fight is about whether these people get access to drugs. Those who are trying to stop these people from getting access to drugs are killing these women, and the trade officials who try to stop these women from getting access to drugs are killing these women.

Now, are intellectual property rights the only problem? No, there are a lot of problems. The Pfizer presentation was dead on about the range of the problems.⁵¹ It is money, it is cultural attitudes, it is everything you can possibly imagine. And no matter what I do, or no matter how successful our campaign is, most of these women are

⁴⁸ See Statement of James Love Before the Subcommittee on Criminal Justice, Human Resources and Drug Policy, Committee on Government Reform on What is the United States' Role in Combating the Global HIV/AIDS Epidemic?, July 22, 1999, available at <http://www.house.gov/reform/cj/hearings/99.7.22/Love.htm> (stating that a quarter to a fifth of the pregnant women in South Africa are testing positive for HIV/AIDS).

⁴⁹ *Id.*

⁵⁰ James Love is referring to a slide regarding current initiatives of the Consumer Project on Technology Campaign for Access to Essential Medicines. Information about the campaign and current initiatives may be found at <http://www.cptech.org>.

⁵¹ See remarks of Robert Mallett, *supra* notes 20-47 and accompanying text.

going to die—not just in South Africa, but also throughout Africa. South Africa is actually one of the few places you have much hope to extend much treatment because the per capita income is over \$3,000 per person.⁵²

Now, what do I work on? I do not work on everything; I just work on a couple of narrow things. I work on issues about pricing and intellectual property rights.

[Slide] Now, competition is what drives prices. This is a Pfizer drug.⁵³ This is the first big campaign on a drug related to AIDS.⁵⁴ In 1998, it cost 200 baht in Thailand.⁵⁵ It is used for cryptococcal meningitis. Ten percent of late-stage AIDS patients get this because they did not have triple therapy in Thailand. Blindness, death, terrible headache—they said it is like your head explodes. That is the disease. It was 200 baht. Nobody could get it.

The NGOs removed exclusivity. The price dropped to 6 baht through competition in nine months.⁵⁶ This galvanized the NGO community. This was the original product that led to the focus on dropping the barriers to competition to bring down prices. This was concrete evidence of the benefits of succeeding on these issues.

⁵² See World Bank Report on Countries: South Africa, The World Bank Group, Sept. 2000, available at <http://www.worldbank.org/afr/za2.htm> (stating that South Africa's per capita income was about \$3,170 in 2000).

⁵³ See Pfizer Inc, *Diflucan Product Information*, available at <http://www.pfizer.com/hml/pi's/diflucanpi.pdf>. The Pfizer drug is Diflucan; its generic name is fluconazole.

⁵⁴ See Pfizer Press Release: Pfizer to Offer Diflucan Antifungal Medicine at No Charge to HIV/AIDS Patients in 50 Least Developed Countries Around the World, June 6, 2001, available at <http://www.pfizer.com/pfizerinc/about/press/nochargediflucan.html>.

⁵⁵ See Anjira Assavanonda, *NGO's Rally Against Patent Law Changes, Call Upon U.S. to Stop Pressuring Thailand*, BANGKOK POST, Sept. 5, 1998, at 2, available at <http://www.cptech.org/ip/health/cl/bangkokpost.html>. (stating that the cost of one-year treatment with Diflucan at the 1998 market price in Thailand was 100,000 baht or U.S. \$2,500, which was unaffordable by the average Thai family).

⁵⁶ See Daniel Berman, *The Biz of AIDS, Geography Lessons*, POZ, Mar. 4, 2001, available at <http://www.poz.com/archive/april2001/inside/geography.html> (last visited Mar. 8, 2002) (noting that a Medecins sans Frontieres campaign conducted a study of the price of Diflucan in eight countries and found that a Thai AIDS patient could buy the generic version of Diflucan for 29 cents per capsule, while a Guatemalan pays \$27.60 for the same dose of the antifungal drug).

In this case, it was not even a patent in Thailand. It was a U.S. Government mandatory exclusive marketing agreement that we forced Thailand to do through our trade officials.⁵⁷

[Slide] This is another story on competition.⁵⁸ Brazil has a lot of AIDS patients, the only place in the developing world that pays for triple therapy for poor people, for everyone who needs it.⁵⁹ In 1996 they were forced to change their patent law in patent pharmaceuticals, so all the drugs prior to then are off patent.⁶⁰ Now, they have never issued a compulsory license, but they were able to buy generic versions of AIDS drugs from Indian, Chinese, Korean, and Brazilian suppliers, whoever, for the older drugs.⁶¹

When they started doing this, it created a market. In the beginning, the prices were not that good from the generic suppliers because they did not know how to do it, they were not that efficient, there were not that many of them.

For example, in 1999 the per-kilo price of 3TC, the most patented antiretroviral single drug in Africa, was \$10,000 per kilo, and then earlier this year it was \$700 per kilo.⁶² The bottom fell out of the market for raw materials in Brazil because of competition.⁶³ It took three years for that to happen.⁶⁴ That lowered the price in Africa,

⁵⁷ See generally Pierre Chirac, Working Compulsory Licensing According to TRIPS, The Essential Drug Candidates, Internal Working Document for Medecins Sans Frontieres, Nov. 25, 1999.

⁵⁸ James Love is referring to data on access to AIDS/HIV drugs in Brazil.

⁵⁹ See AIDS Triple Therapy for Less Than \$1 a Day: MSF Challenges Pharmaceutical Industry to Match Generic Prices, Medecins Sans Frontieres, Feb. 7, 2001, available at <http://www.doctorswithoutborders.org/pr/2001/02-07-2001.html> (noting that the government of Brazil has successfully cut AIDS deaths in half, largely due to its ability to produce generic AIDS medicines).

⁶⁰ Brazil did not extend patent protection to pharmaceuticals until they were pressured by the United States to do so. See MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 4 (1996).

⁶¹ See Chakravarthi Raghavan, *U.S. Beats a (Tactical) Retreat Over Brazil's Patent Law*, Third World Network, June 2001, available at <http://www.twinside.org/sg/title/tactical.htm> (noting that Brazil has never actually issued a compulsory license).

⁶² See Affidavit in Support of Brief of Amicus Curiae, at 26, Pharmaceutical Mfrs' Ass'n of South Africa v. The President of the Republic of South Africa (Case No. 4183/98), available at <http://cptech.org/ip/health/sa/loveaffidavit>.

⁶³ *Id.*

⁶⁴ *Id.*

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and that is why Africa has treatment problems, because a country with higher income moved first and created the market.

[Slide] These are the prices for Nevirapine, 3TC [Lamivudine] and d4T [Stavudine].⁶⁵ This is the cheapest possible three-drug cocktail to manufacture in Africa.⁶⁶ You can buy it in one pill form taken twice a day.⁶⁷ This is a copy of it from Cipla, an Indian manufacturer, for \$0.67 a day.⁶⁸ I can buy this for \$0.67 a day in bulk, and I believe if you had competition the price would fall more.

In the United States it is around \$10,000.⁶⁹ In May of this year the prices that businesses were paying for their employees for this cocktail was \$3,000.⁷⁰ This was after the trial in South Africa, after all these discounts. The best donation price you can get for this cocktail is about \$730, or about three times what you can get it for from the Indian manufacturer, and that is the so-called “donation price.”

⁶⁵ See Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign, Health Gap, Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa, Oct. 16, 2001 [hereinafter *CPT Comment on Attaran/Gillespie-White*], available at <http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html>; Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NNRTI), known commercially as Viramune. Lamivudine (3TC) is a nucleoside analogue reverse transcriptase inhibitor (RT), known commercially as Epivir. Stavudine (d4T) is also a nucleoside analogue reverse transcriptase inhibitor, known commercially as Zerit. James Love, Background Information on Fourteen FDA Approved HIV/AIDS Drugs, available at <http://www.cptech.org/ip/health/aids/druginfo.html>.

⁶⁶ See Memorandum from James Love to Gro Harlan Brundtland and David Nabarro re: Request that WHO Seek Compulsory Licenses for 5 Essential Antiretroviral Products in Sub-Saharan Africa, Oct. 7, 2001 [hereinafter *Love Memo to Brundtland and Nabarro*], available at <http://lists.essential.org/pipermail/ip-health/2001-October/002012.html>.

⁶⁷ *Id.*

⁶⁸ See Cipla Offers to Provide Low Cost Triple-Combination Therapy for HIV/AIDS, available at <http://www.cptech.org/ip/health/cipla> (noting that Cipla has offered to supply triple-combination therapy for HIV/AIDS for \$350 per patient, per year to Medicins San Frontieres).

⁶⁹ See Trade Campaign—Cut the Cost Campaign, Facts and Pricing System of AIDS Drugs, Oxfam, available at <http://www.oxfam.org/hk/english/campaigns/trade/001.shtml> (noting that yearly treatment cost for AIDS drugs ranges between U.S. \$10,000 and U.S. \$15,000).

⁷⁰ James Love is referring to a slide reporting that in May, 2001, businesses in the United States were paying \$3,000 for HIV drugs.

Now, why is this important? Because \$700 looks a lot cheaper than \$10,000. It is like more than 90 percent off, the Glaxo donation price, but it is still too high for Anglo American, who is trying to decide whether to provide triple therapy to their employees, because they have doctors, they have employees, they have a whole infrastructure for doing it for mine workers.⁷¹ We negotiated a deal with them for various products from Indian manufacturers.⁷² Anglo-American announced a week or two ago, because there are still patents in place in South Africa, that they will not provide triple therapy to the workers in Botswana, South Africa, and other places where these cheap cocktails are blocked by patents.⁷³

[Slide] This just shows you in a filing a few weeks ago in South Africa in a compulsory licensing case the current retail differences for 3TC, AZT, and 3TC-plus-AZT (Combivir) between Glaxo's products and Cipla's products.⁷⁴ These products and the Cipla products would fall if you had competitive entry because they would have competition from Ranbaxy and a bunch of other firms.⁷⁵

[Slide] Why do they vary so much? Well, I said the least expensive ones were patented before 1996 and it was the Brazil purchases that generated suppliers which created the competitive market. That is why Efavirenz, Nevirapine, Abacivir, some of the newer products, are really high priced, because there is no big market

⁷¹ GlaxoSmithKline (GSK) is a research-based pharmaceutical company headquartered in the UK and with operations based in the U.S. The company controls an estimated seven percent of the world's pharmaceutical market. See GlaxoSmithKline homepage, available at <http://corp.gsk.com/>. Anglo American is a British-owned mining company with 160,000 employees in South Africa. It is estimated that twenty-one percent of Anglo American's employees are HIV positive. Consumer Project on Technology, South Africa and Access to Pharmaceutical Drugs, available at <http://www.cptech.org/ip/health/sa/index.html>.

⁷² See James Love, Cipla-Anglo Discussions, May 7, 2001, available at <http://lists.essential.org/pipermail/pharm-policy/2001-May/001018.html>; see also Mark Schoofs, *Mining Firm Anglo American Offers AIDS Drugs to Workers*, WALL ST. J., May 7, 2001, at <http://www.aegis.com/news/wsj/2001/WJ010504.html>.

⁷³ See James Love, Consequences of High Private Sector Prices: FT on Anglo and ARV tx for workers, Oct. 9, 2001, available at <http://lists.essential.org/pipermail/ip-health/2001-October/002045.html>.

⁷⁴ See James Love, CIPLA-Medpro Complaint to RSA Competition Commission, Oct. 8, 2001, available at <http://lists.essential.org/pipermail/ip-health/2001-October/002026.html>.

⁷⁵ Love Memo to Brundtland and Nabarro, *supra* note 66.

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in which they can sell them.⁷⁶ So what most of the activists want is to open up the South Africa market, because if the South Africa market is opened up, you get the economies of scale and the volume, because they have patients plus income in South Africa. So South Africa—and everybody knows it—is key to getting cheap new AIDS drugs on the market.

Now, other reasons. You have to look at the doses in the drugs, how many milligrams do you have to do.

[Slide] Some molecules are cheaper to manufacture than others. Protease inhibitors are expensive to manufacture, non-nucleosides cheaper to manufacture.⁷⁷ And it takes time to figure out how to do it, so you have to wait sometimes.

[Slide] Where do the companies file patents in Africa? This is basically a rebuttal of a paper you have not even heard yet, so then Amir gets to rebut my rebuttal and present his paper at the same time.⁷⁸

This is an example. It is uneven in Africa. Depending upon how you count the combinations, there are fifteen or sixteen, something like that, different products in antiretroviral treatment in the continent of Africa.⁷⁹

Left off there is a three-drug version of Abacivir, 3TC, and AZT, which is a very important combination, but we do not have any data because it was not included in the PhRMA or the Amir surveys.⁸⁰ Anyway, these are the most patented ones.

There are a lot of products that have very few patents. Some products have zero patents, like Norvir, but of course the better

⁷⁶ *Id.*

⁷⁷ *Id.*; see also generally James Love, *How Much Does it Cost to Develop a New Drug*, Paper delivered April 2, 2000 to Medicins Sans Frontieres Working Group on Research and Development, available at <http://www.cptech.org/ip/health/econ/howmuch.html>.

⁷⁸ See generally Love *Memo to Brundtland and Nabarro*, *supra* note 66.

⁷⁹ *Id.*

⁸⁰ *Id.*; see also Amir Attaran and Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JAMA* 1886 (2001) [hereinafter *Attaran & Gillespie-White*].

version of Norvir is patented in South Africa, but only in one country.⁸¹

Efavirenz is only just in two countries.⁸² So there are ddi [Didanosine], d4T [Stavudine]. There are some that are just in one or two countries, and these are in lots of countries.⁸³

So the question is: can you just get the ones that are off-patent and forget about those that are on-patent? The answer is: Well, not really, because the cheapest ones, the key ones, Combivir, 3TC, Nevirapine, Abacavir, and AZT, those are key to any regime based on simple-to-use.⁸⁴

Here are some other items I want to talk about.

[Slide] Where are the patents filed?

In South Africa, where they have fifteen or more products under patent, everything but Norvir, not including the new version, which is under patent, everything is basically patented in South Africa.⁸⁵ That is 17 percent of the AIDS patients in sub-Saharan Africa.⁸⁶ It is 41 percent of the region's GNP.⁸⁷ Forty-one percent of the GNP for sub-Saharan Africa is in one country, and that is where all the patents are.⁸⁸

⁸¹ See *CPT Comment on Attaran/Gillespie-White*, *supra* note 65. Norvir (ritonavir), produced by Abbott Laboratories, is used in combination with other antiretroviral medicines to treat HIV infection. See Information about Norvir, available at <http://www.norvir.com/hiv/hiv0044.htm>.

⁸² See *CPT Comment on Attaran/Gillespie-White*, *supra* note 65. Efavirenz is a non-nucleoside reverse transcriptase inhibitor sold under the name Sustiva by Bristol Myers Squibb Company. See Information about Efavirenz, available at www.sustiva.com.

⁸³ See *CPT Comment on Attaran/Gillespie-White*, *supra* note 65.

⁸⁴ See generally *Love Memo to Brundtland and Nabarro*, *supra* note 66.

⁸⁵ *Id.*

⁸⁶ See CPT Table: Number of ARVs Patented in Each Country in Sub-Saharan Africa, Along with Figures on PWAs, Population, and Income, Consumer Project on Technology, available at <http://www.cptech.org/ip/health/africa/jama-patents-table.html>; see also David Satcher, MD, *The Global HIV/AIDS Epidemic*, JAMA, Apr. 28, 1999, available at <http://jama.ama-assn.org/issues/v281n16/full/jsg91001-1.html>.

⁸⁷ See CPT Table: Number of ARVs Patented in Each Country in Sub-Saharan Africa, Along with Figures on PWAs, Population, and Income, Consumer Project on Technology, available at <http://www.cptech.org/ip/health/africa/jama-patents-table.html>.

⁸⁸ *Id.*; see also *CPT Comment on Attaran/Gillespie-White*, *supra* note 65.

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If you go to a level of four products or more—and that is going to include 3TC, that is going to include Nevirapine, that is going to include the products that are used for the low-cost cocktails—46 percent of the patients, 56 percent of the GNP.⁸⁹

[Slide] If you go to where there is any patent coverage at all on an AIDS drug, which means they have a patent system in place and they are beginning to, after trade pressures, issue patents on AIDS drugs, in Africa, you are talking about 72 percent of the AIDS patients and 87 percent of the GDP for the region.⁹⁰

[Slide] What type of cocktails are blocked the most? Those that are the least expensive to manufacture, those that are the easiest to take, and those that have the fewest compliance problems. For example, one pill twice a day—those are all blocked. Eighteen pills a day with dietary restrictions—you can get some of those off-patent. But they are so expensive to manufacture. Unfortunately, there is a difference between the cheapest and what is patented. And the treatment activists are quite focused on these things.

[Slide] The WTO agreement is the most important thing.⁹¹ Countries are supposed to be able to do whatever they want. This is a law that requires us to change the South Africa law.

[Slide] This is a 301 report, where we brought a trade sanction against South Africa for letting the doctors speak at the World Health Assembly and called for basically more access to medicine, that it is a barrier to trade to allow Doctor Olive Shoshona or Minister of Health Nkozasana Dhlamini Zuma to go to the World Health Assembly, or Dr. Ian Roberts, and argue to other doctors, their colleagues, that the trade rules are impeding access to medicine

⁸⁹ *CPT Comment on Attaran/Gillespie-White, supra* note 65.

⁹⁰ *Id.*

⁹¹ *See TRIPS, supra* note 16.

in Africa.⁹² That actually got them 301 listed. As a result, Dr. Zuma had to take herself off an AIDS panel a few months later.⁹³

[Slide] This is an Executive Order that we got, part of our campaign.⁹⁴ We have had a lot of successes and failures, fixed things, on the campaign. A lot of bilateral pressures going on all over the place.

[Slide] What is compulsory licensing? That is when a judge issues a non-voluntary use of a patent. Now, the story about Cipro is this: the U.S. Government says it needs a stockpile of Cipro; they would like to have it for 10 million people.⁹⁵ The branded manufacturer, Bayer, says it can make about 15 million pills a week.⁹⁶ I do not know if you do any arithmetic, but it takes a long time to get to 1.2 billion pills from that. So unless the government has some agreement with Bin Laden or something not to start dropping weaponized anthrax all over the place or something like that, then one might think that time is of the essence.

It turns out there are five companies in addition to Bayer that are already approved by the United States Food & Drug Administration to manufacture that product in the United States.⁹⁷ It turns out Cipla and Ranbaxy are two of the companies that are involved in this through the supply chain one way or another.⁹⁸ I do not know about Ranbaxy, but Indian firms are involved in this; Barr Pharmaceuticals;

⁹² See USTR Press Release: USTR Announces Results of Special 301 Annual Review, Office of the United States Trade Representative, Executive Office of the President (Apr. 30, 1999), available at <http://www.ustr.gov/releases/1999/04/99-41.html>; see also 1999 USTR 301 report on South Africa, annotated, available at <http://www.cptech.org/ip/health/sa/sa301-ap99.html>.

⁹³ *Id.*

⁹⁴ See Text of the Africa/HIV/AIDS Executive Order 13155, available at <http://lists.essential.org/pipermail/pharm-policy/2001-January/000613.html>.

⁹⁵ See Melody Petersen and Robert Pear, *A Nation Challenged: The Antibiotic; Production of Cipro Is Being Tripled, German Company Says*, N.Y. TIMES, Oct. 17, 2001, at B7.

⁹⁶ *Id.*

⁹⁷ See *Teva Ready to Produce Generic Treatment of Anthrax Treatment*, JERUS. POST, Oct. 18, 2001, at 12.

⁹⁸ *Id.*

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Teva—they all have licenses to do this, but they have to overcome the patent.⁹⁹

[Slide] The U.S. Government could issue a compulsory license any time they wanted to under 28 U.S.C. § 1498 authority for government use.¹⁰⁰ We have the best government use provision in the world in terms of the decision-making process—and we could immediately have five companies start supplying the stockpile.

Now, why do we not do that? We do not do that, and we are putting lives in America at risk, because Tommy Thompson is personally deeply involved in efforts to stop the WTO from passing a good pro-public health access resolution at Doha next month.¹⁰¹ His efforts are all designed to not send a signal that we are the biggest hypocrites on earth, because we are going to import cheap medicine for our little public health crisis and we do not want them to import cheap drugs from India for their public health crisis. So because we want to make that point to the Africans, we want to keep those pregnant women in every Goddamn country there, and those kids who are going to be born infected, whatever, orphanages that cannot get medicine, we are going to tell those people in those areas that they cannot do that and “Look, we are willing to put all these Americans at risk, too.”

That is the power of that idea, and that is what you are being trained in this school in intellectual property to respect. That is what is called respect for intellectual property. That is a deep level of respect for something. That is what it is.

Now I am going to turn over the mike and you are going to hear Amir basically present why this is not important. The theory you are going to hear is the problem is that people are poor, and so high

⁹⁹ *Id.*

¹⁰⁰ 28 U.S.C. § 1498 (1994).

¹⁰¹ See Sabin Russell, *U.S. Push for Cheap Cipro Haunts AIDS Drug Dispute*, S.F. CHRON., Nov. 9, 2001 (discussing 2001 World Trade Organization ministers meeting in Doha, Qatar and actions of Health and Human Services Secretary Tommy Thompson, who reportedly threatened to sidestep Bayer’s patent to win a 50-percent price cut on 300 million Cipro pills destined for the U.S. stockpile of drugs against Anthrax in the wake of the September 2001 terrorist attacks on the United States).

prices (1) are not a barrier, because the poor do not mind paying three or four or ten times as much as they have to; (2) that somehow making the poor pay high prices draws donor funds into countries, and so if you actually insist on high levels of drug prices, somehow you are going to get some kind of donor aid, that somehow there is some benefit to that; and (3) lastly, that the off-patent drugs are equally good substitutes, without any reference at all to any reality in terms of the real practical things in the ground of the kind of cocktails people want or why anybody would want to limit the range of the products in the first place.

Thank you.

MR. WARNER: Thank you. Let's go on to the next speaker. I thought that was very helpful.

Amir, you get a chance to speak for yourself this time.

MR. ATTARAN: That would be very nice.

I am Amir Attaran. I am a researcher and lecturer in the Center for International Development of Harvard and also the Kennedy School of Government at Harvard.¹⁰² I am going to be speaking to you today about my conclusions, having been in this field now for several years, and even at one time having been Jamie's colleague.

What I am going to say is rather at variance with what he said. What I am going to say is detailed much better than I can possibly give it to you in a few minutes here in a paper that has been circulated. Margaret tells me it has been circulated, and I should thank her for that. It was published in the *Journal of the American Medical Association* two days ago, as the lead article actually, a special communication to the *Journal*.¹⁰³

What I will be talking about is the relative contribution of international-aid finance and patents to the deplorable state of affairs we have today, that very few people in Africa are being treated for AIDS.

¹⁰² The John F. Kennedy School of Government Web site may be accessed at <http://www.ksg.harvard.edu>.

¹⁰³ *Attaran & Gillespie-White, supra* note 80.

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[Slide] How deplorable is it? It is this bad. What you see here on this graph are two lines.¹⁰⁴ The dashed line at the bottom is the annual number of AIDS deaths in the United States. The last year, which you cannot read, is 1999. The solid line is sub-Saharan Africa. That is the difference between Africa and a rich country right now. You might see, just around here, a small downward deflection in the U.S. trend. That is actually a 70 percent reduction in deaths because of treatment. And you certainly do not see that in the Africa trend.¹⁰⁵

[Slide] I want to explain briefly, just as an educator, what I think the various essential components are to achieving treatment in Africa for people with AIDS. It is like a chain. There are several things that must be got right. To get one of them wrong is to fail to arrive at the desired result: people taking pills and people not dying because of that.

I agree with Jamie that the very first piece of the chain has been—and he showed some evidence of this—to get competition into markets so that prices may be able to come down. That is the orthodox view. Now, I am going to qualify that in a moment, but the orthodox view is that competition, because you have no patent or because you are able to license the patent to another party, enables competition.¹⁰⁶ In the orthodox model competition for a drug needs to be followed up by registration for the generic products.

Now generally, the brand-name products in developing countries have passed regulatory scrutiny and with the national drug regulatory authorities—the equivalent of the FDA—in an African country, and are approved for use.¹⁰⁷ That is seldom the case with generic products until, of course, they go through all the paperwork hurdles

¹⁰⁴ Amir Attaran is referring to a chart depicting a comparison between the average viral genetics, access to public health and prevention (or lack thereof), poverty and inequality (or lack thereof), and access to treatment and prevention (or lack thereof), in the United States and Sub-Saharan Africa. Predictably, the United States' average viral genetics and access rates reflect greater access to AIDS/HIV treatment in the United States. *See also Attaran & Gillespie-White, supra note 80.*

¹⁰⁵ *Id.*

¹⁰⁶ *Attaran & Gillespie-White, supra note 80.*

¹⁰⁷ *Id.*

to be recognized as quality suppliers able to meet that country's needs. That is not to say they cannot do it, they can absolutely do it, but that is an essential step before the generic can be used. One may not use, under law, a product that has not been registered.¹⁰⁸

So competition and registration are prerequisites.

[Slide] And that, once you have registered the product and are able to sell it in the country, this leads to, as I say, the orthodox outcome: market forces of competition drive down drug prices. That is Economics 101, plain and simple. But that is not the only way things can happen.

Another way they can happen is you can set at naught the first two steps. Rather than going through those two steps of the chain, what can happen is policy decisions can be made to cut prices, to discount heavily, or to donate for free, and that has happened, as Mark told us, for quite a lot of the antiretroviral drugs.¹⁰⁹ That short-circuits the process favorably in a way, and it leads to lower prices without the essential steps of competition or registration (registration having been done already for the brand-name products in most cases). But it gets you to the same point, at least qualitatively, perhaps not quantitatively, in that drug prices have come down.

[Slide] But, in reality, in the world we would like to see both going on at the same time. I think there is no dispute about that. We would like to see competitive markets function and we would like to see prices come down by fiat, by policy if you will, by discounting and by donations.

[Slide] Regardless of how we have done the pricing issue, we move on to the next issue: aid funding. Who is going to pay? We have heard very clearly from Bob this morning that African countries are impoverished, and indeed they are.¹¹⁰ I come from the Harvard Center for International Development. I will tell you that is the case.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ See remarks of Robert Mallett, *supra* notes 20-47 and accompanying text.

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And, unfortunately, this is a matter that is out of the hands of the developing countries. It is the rich governments—the United States, Canada, Western Europe, Japan—that have the means to finance these therapies. I will show you some numbers later on how expensive these therapies are.

If you get the money to pay for even the discounted drugs and deliver them in the clinic, then you have the problem of building capacity. It is a challenge. Many developing countries have few doctors, few clinics, little research capacity, labs, and also the enormous issue of stigma.¹¹¹ You have to entrench the idea in people's thoughts that AIDS is not a disease to be simply suffered through and die quietly of, but that it is appropriate for them to come forward and seek treatment. And there is an enormous stigma against them doing so, believe it or not. I found it surprising until I actually witnessed it.

So all of these things must be right. This chain must be complete. And the weakest link in the chain will disrupt progress towards this goal.

[Slide] This is a woman in rural Haiti who was lying on her death bed when one of my colleagues, Dr. Paul Farmer of Harvard University,¹¹² decided to treat her in a country where she could not possibly afford treatment.

[Slide] You can see how she looks only months later. I have not labeled these “before” and “after,” but I think it is self-evident.

So why is this not happening more often?

[Slide] Well, in this chain there are two hypotheses where the weakest links are.

Jamie has just argued that this link is broken [points to link labeled “competition”], that there is not competition, that patents are impeding the availability of competition and, therefore, the

¹¹¹ See *Attaran & Gillespie-White, supra* note 80, at 1890.

¹¹² Dr. Paul Farmer is a Professor of Medical Anthropology in the Department of Social Medicine at Harvard Medical School. He received his M.D. and Ph.D from Harvard University in 1990.

availability of drug. In some circumstances he will be right. I am going to concede that. I am going to give you quantitative data on how often he is right and how often he is not.

I argue that this is the bigger problem right now [points to link labeled “international aid”], that aid funding is the problem. The evidence of that is even where drugs have been heavily discounted or donated, they are not being used right now because there is no money to implement their use.

[Slide] So let’s look. Here are some data from the study that I mentioned, the one that is published in the *Journal of the American Medical Association* this week.¹¹³

What we did is we surveyed, for the very first time—it is surprising this had not been done before—

MR. LOVE: It has.

MR. ATTARAN: —the patent status of fifteen drugs in fifty-three countries. You build a two way matrix or chart, if you will: fifteen drugs across this way on the grid, fifty-three countries that way [vertically], and you mark with a little tick mark, a little check, at the intersection where a drug is patented. It is not rocket science. It is hard work to collect the data, but it is not rocket science.

What we find is that when we complete this grid, each of the fifteen drugs is actually patented in very few countries.¹¹⁴ The median number of countries a drug is patented in out of the fifty-three countries is three, and the mode is one.¹¹⁵ There are exceptions. Products from Boehringer Ingleheim, from Glaxo SmithKline, and from Pfizer are patented more often than the others.¹¹⁶

Now, if we look at the subset of countries where there are patents, forty of them out of the fifty-three countries—thirteen countries have

¹¹³ *Attaran & Gillespie-White, supra* note 80.

¹¹⁴ *Id.* at 1888.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

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no patents at all.¹¹⁷ If we look at the forty where there are patents, what we find is that in those countries it is still a small number of drugs that are patented.¹¹⁸ So in the subset of countries with patents, and therefore, certainly patent laws, of the fifteen drugs we might have found patented, generally it is few—the median and the mode is four drugs out of the fifteen. The exception being South Africa, where thirteen of the fifteen are patented.¹¹⁹ Overall, in that grid of about 800 intersections between countries and drugs, about 21.6 percent coverage is found for patents.¹²⁰

[Slide] So when we seek to assign weight to whether it is this link [points to link labeled “competition”] or this link [points to link labeled “international aid”] that is broken, we find that at this link [“competition”] we only have 21.6 percent patent coverage.¹²¹ Jamie made the point that that 21.6 percent is largely preclusive of using antiretroviral therapy in triple therapy, or “HAART” you may have heard it called, the combination therapy.¹²²

[Slide] So we took these patent data we had and we tested them against several drug regimens. We did not test all the combinations; there are far too many. What we did is we gave preference to those regimens that are recommended by the Expert Committee of the Department of Health and Human Services.¹²³ That is the second column. Some regimens are “strongly recommended,” some are “recommended as alternative,” and some are not recommended at all. We also gave preference to those in the last column where good-quality clinical trial data were found showing the safety and efficacy of these regimens. These are not all the regimens that satisfy those criteria. This is a subset, but we tried to make it a reasonably representative one, and it includes the best-case and the worst-case scenarios.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Attaran & Gillespie-White, *supra* note 80, at 1888.

¹²¹ *Id.*

¹²² See generally Paul Farmer et al., *Community-Based Approaches to HIV Treatment in Resource-Poor Settings*, 358 LANCET 404 (2001); see also CPT Comment on Attaran/Gillespie-White, *supra* note 65.

¹²³ Attaran & Gillespie-White, *supra* note 80, at 1890.

[Slide] What we see—look at the first two regimens, the first two lines, starting with d4T. Those are strongly recommended.¹²⁴ What we see is that in fifty-one out of fifty-three African countries there is no patent barrier to those, and in fifty-two out of fifty-three countries only one of the three or four components is patented.¹²⁵ So if you can live with one patent among three or four drugs in a combination therapy, then in fifty-two out of fifty-three countries you find that condition fulfilled.

And that is true for some of the other combinations as well. The worst-case scenario is AZT+3TC+Nelfinavir (NEL), which is four lines down. Those are three extremely heavily patented products. There you see that, indeed, about half of countries in Africa have one patent.¹²⁶

[Slide] Jamie said that Combivir, AZT, and Abacivir are basic to any regimen. That is absolutely incorrect. What we see here are several regimens, a lot of them, and I could list more, that are not based on AZT, Abacivir, Combivir, and are “strongly recommended” by the Department of Health and Human Services.¹²⁷

I am an immunologist and I am an lawyer, and I can tell you, going through the medical literature, that while AZT is a very important drug, it is not basic to any regimen at all. Certainly it is important, in many regimens, but there are alternatives to it.

[Slide] These are the data, just to show you in graphical form what the patent coverage looks like.¹²⁸ You will see that there is an interesting juxtaposition that can be made, a natural experiment: South Africa with thirteen patents, in the red; and next door to it, Namibia and Angola and Mozambique with zero patents.¹²⁹ Other countries have zero patents too, and most of them have a few.¹³⁰

¹²⁴ *Id.*

¹²⁵ *Id.* at 1888.

¹²⁶ *Id.* at 1890.

¹²⁷ *Id.*

¹²⁸ *Id.* at 1899.

¹²⁹ *Id.*

¹³⁰ *Id.*

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But let's take the extremes and let's argue from the extremes, where we have heavy patenting and thirteen patents in one country, South Africa, and zero patents in two neighboring countries, Namibia and Mozambique. Well, we can do some reasoning here. If patents were as a matter of fact—and this is an activist claim, if I can caricature it as such—if patents were impeding access to treatment, there should be an inverse correlation between patent coverage and treatment access, such that in South Africa you might have very little treatment, but in neighboring Namibia where you have no patents you could have a lot of treatment. That would be the expected result if patents were the barrier on that chain of events I discussed earlier.

And yet, what we find is that is not the case. All across Africa there are 25,000 people being treated out of 25 million with HIV.¹³¹ That is a WHO statistic.¹³² That is 0.1 percent. Can I just do some rounding and say that 0.1 percent is for all intents and purposes zero? So we are not seeing an abundance of treatment where there are no patents and a scarcity of treatment where there are.

Similarly, the industry claim sometimes, if I may caricature that as such, is that global patentability and patent laws are essential to doing research and development (“R&D”). It is interesting that in these data several countries did have patent laws, and those laws were not used to their fullest, and yet R&D proceeded. Fifteen drugs at least were invented, even as existing patent laws were not used by the companies. So that casts some doubt on whether in all cases global patentability is necessary.

The reason those two things are true is because at the end of the day it is finance, not law, that is the greater determinant of treatment access and the economics of research and development.

[Slide] And just to show you very quickly how impossible it is for these countries to afford treatment on their own, what you see on this slide, in purple, are a bunch of African countries and their public health budgets.¹³³ These countries are down at about \$5.00 per year.

¹³¹ See *UNAIDS Epidemic Update*, *supra* note 4.

¹³² *Id.* The Study referred to was a product of the Joint United Nations Programme on HIV/AIDS, which includes the World Health Organization.

¹³³ Amir Attaran is referring to a slide on which the public per capita health expenditure

The average African country has a public health budget of \$10.00 per year, per person, to spend on AIDS, malaria, TB, prenatal care, postnatal care, vaccination, and so forth.¹³⁴ And the very cheapest treatment regimen—drug only, not implementation cost—is about \$350.¹³⁵ There is no way these countries can pay for this without help. And if we look at the actual treatment costs right now in Botswana, a country that is doing it—drug plus implementation is about \$1,600 per year.¹³⁶

[Slide] And meanwhile, this is the amount of foreign aid that the rich countries are giving to the poor. This is from a paper I did with Jeff Sachs earlier this year.¹³⁷ It is about \$5.00 per person in Africa with AIDS. That is how much Europe, Japan, the United States, Canada, everyone combined, is providing for AIDS.¹³⁸ In 1999 the amount was \$120 million, or about enough to build five miles of freeway, from all the rich countries combined.¹³⁹

You can see the trend in foreign aid is bad.

[Slide] So here are the conclusions, because my chairman wants me to wrap up. What we show by these data is that currently, patents in Africa are generally not the barrier to treatment access for antiretroviral therapy. South Africa is an exception.

But I want you to be very careful to note that this is a qualified statement. I am not saying in this talk that patents are never a

versus the lowest drug cost, versus the cost of care and treatment with HAART is depicted for various countries; see also Attaran & Gillespie White, *supra* note 80.

¹³⁴ See Attaran & Gillespie-White, *supra* note 80.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Amir Attaran & Jeffrey Sachs, *Defining and Refining International Donor Support for Combating the AIDS Pandemic*, 357 LANCET 57 (2001). Dr. Jeffrey Sachs is a Galen L. Stone Professor of International Trade, Faculty of Arts and Sciences, and Director of the Center for International Development, Harvard University. He received his B.A. from Harvard in 1976, an M.A. from Harvard University in 1978, and a Ph.D from Harvard in 1980.

¹³⁸ Amir Attaran & Jeffrey Sachs, *Defining and Refining International Donor Support for Combating the AIDS Pandemic*, 357 LANCET 57, 59 (2001).

¹³⁹ *Id.*; see also Attaran & Gillespie-White, *supra* note 80, at 1891 (“It is remarkable that the world’s richest nations of North America, Western Europe, and Asia-Pacific together set aside only \$74 million specifically for African AIDS in 1998—about \$3 per HIV-infected African, or what it costs to build 3 miles (5KM) of rural freeway.”).

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barrier. That is not the message. That is a much larger question than I could answer with a case study of one category of drug in one continent at one year, and it is clear that in other circumstances patents might be a barrier.

But for the present purposes, anyone caring about treating people with AIDS in Africa had best pay a great deal more attention to the finance barriers and to that scarcity of aid—the five miles of freeway annually—than the patent issues.

[Slide] If we do not do it, this is what we are going to get. That is the population structure of Botswana before and after AIDS: 80 percent of the adults in some age categories will die.

So we have to do it.

Thanks very much.

MR. WARNER: The next speaker is Professor Visser from South Africa.

PROFESSOR VISSER: Thank you, Chair, and thank you for the invitation to be here today.

Thus far this morning we have been talking mainly economics. I am overwhelmed by the economics, and also by Amir's conclusion basically, and I think he is right that at the end of the day the law has very little to say or to do in this context; it is ultimately a question of finance.

Let me start off just by giving you some figures to put the South African situation in context: The Medical Research Council in South Africa earlier this week released a report stating that, according to the latest research in South Africa, HIV/AIDS is the biggest killer in South Africa.¹⁴⁰ It accounted last year for 25 percent of all deaths in South Africa.¹⁴¹ In the largest public hospital in South Africa, one in every four babies are born HIV-positive.¹⁴² The life expectancy in

¹⁴⁰ The Impact of HIV/AIDS on Adult Mortality in South Africa, the Medical Research Council of South Africa 6 (2001), available at <http://www.mrc.ac.za/bod/index.htm>.

¹⁴¹ *Id.*

¹⁴² *Id.*

certain parts of the country has been reduced to just under forty years.¹⁴³

It is against this background that the South African Government has to operate a public health policy to deal with HIV/AIDS. That is the background, I think, to the legislation that I want to talk to you about; also I want to indicate to you the international context and also the South African context within which the South African Government had to deal with a health problem, and also of course a financial problem, of this magnitude.

Reference was made to the litigation in South Africa between the Pharmaceutical Manufacturers Association and the South African Government.¹⁴⁴ That litigation related to an amendment to the so-called Medicines and Related Substances Control Act of 1965, which is legislation under which a body set up by the South African Government has to give regulatory approval for the distribution of drugs and medicines in South Africa.¹⁴⁵

An amendment was made to this statute by the introduction, and you saw the reference to that, of the so-called Section 15(c) of this legislation, which gave the Minister of Health very wide-ranging powers.¹⁴⁶ I am not going to read you the whole Section, just the introduction. It says: "The Minister of Health may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public," and then it continues, "and, in particular, may, notwithstanding anything to the contrary contained in the Patents Act," and then it gives the Minister powers to regulate parallel importation and also to regulate importation of generic drugs and the substitution of that in treatment regimens in South Africa.¹⁴⁷ So those are the broad powers given to

¹⁴³ *Id.*

¹⁴⁴ *Pharmaceutical Mfrs' Ass'n of South Africa v. President of the Republic of South Africa*, Case No. 4183/98 (High Court of South Africa 1998) [hereinafter *South African Pharmaceutical Case*], available at <http://www.cptech.org/ip/health/sa/pharmasuit.html>. The suit was dropped in 2001.

¹⁴⁵ Section 15(c) of South African Medicines and Related Substances Control Act No. 101 of 1965.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

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the Minister. It is also then provided that the exact exercise of these powers should be detailed in a regulation, still to be issued by the Minister.¹⁴⁸

The Pharmaceutical Manufacturers Association then took the Minister of Health and the South African Government to court to argue for the repeal of this Section in the legislation.¹⁴⁹ Strangely enough, that case was based not on patent law, but on the Constitution, especially on the Section in the Constitution protecting the right of property.¹⁵⁰ I will come back to that. The case was settled out of court, and I think you have a memorandum in the materials handed out today relating to the statement issued by the parties involved relating to the settlement out of court.¹⁵¹

The key test, I think, will still be to see what happens once the regulations have been issued for the exercise of these rights. I think it is too early to claim victory for any one side in this particular dispute. And also, I think that Section 15(c) will probably still have to be tested in the international arena against the provisions of the TRIPS Agreement.¹⁵²

Article 27 of the TRIPS Agreement, as you probably know, gives a very wide obligation to countries to protect patentable subject matter by patent;¹⁵³ and, in Article 28, it prescribes very wide-ranging rights which must be granted to the owners of patents in national legislation.¹⁵⁴ South Africa has complied with both of these requirements.

But then, Article 30 of the TRIPS Agreement provides for the possibility of exceptions to patent rights.¹⁵⁵ I will quote Article 30 to

¹⁴⁸ *Id.*

¹⁴⁹ See *South Africa Pharmaceutical Case*, *supra* note 146.

¹⁵⁰ *Id.*

¹⁵¹ See The Pharmaceutical Manufacturers' Association of South Africa and the President of the Republic of South Africa: Joint Statement of Understanding Between the Republic of South Africa and the Applicants, available at http://www.efpia.org/3_press/20010419.htm#jointsettlement (last visited Mar. 8, 2002).

¹⁵² TRIPS Art. 15(c), *supra* note 16.

¹⁵³ TRIPS Art. 27, *supra* note 16.

¹⁵⁴ TRIPS Art. 28, *supra* note 16.

¹⁵⁵ TRIPS Art. 30, *supra* note 16.

you. Article 30 says, “Members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”¹⁵⁶

Now, the test in Article 30 of the TRIPS Agreement was the subject of a report of the Dispute Resolution Council set up by the World Trade Organization¹⁵⁷ in the *Canadian Pharmaceuticals* case, which dealt with two exceptions in the Canadian Patent Act relating to affordable medicines, the so-called regulatory review exception, which allows people to start applying for regulatory review before the end of the patent term; and also for a so-called stockpiling exception, which allows manufacturers to start stockpiling generic drugs in anticipation of the expiry of the patent term.¹⁵⁸

The panel struck down the stockpiling exception but upheld the regulatory review exception.¹⁵⁹ It again stated very clearly what the three requirements are in Article 30 relating to exceptions to patent rights.¹⁶⁰

In the first part, they said these exceptions must be limited exceptions, and they gave a very strange meaning to “limited,” how to determine whether it is limited.¹⁶¹ It says you determine whether an exception is limited only by reading the text of the exception—you do not look into economics; it is a question of textual analysis only.¹⁶² Then, the exception must not unreasonably conflict with the normal exploitation of the patent.¹⁶³ I think the limitations in that are

¹⁵⁶ *Id.*

¹⁵⁷ Report of the Panel on Canada—Term of Patent Protection, World Trade Organization, WT/DS170/R, May 5, 2000 [hereinafter *Canadian Pharmaceutical Case*], available at <http://www.dfait-maeci.gc.ca/tna-nac/dispute-e.asp#Patent> (last visited Mar. 8, 2002).

¹⁵⁸ *Id.* (stating that Canadian Patent Act, R.S.C., ch. P-4, §§ 44-46 (1985) (Can.), were at issue in the WTO dispute).

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

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clear. And also, it must not unreasonably prejudice the legitimate interests of the patent owner, and the restrictions in that are clear.¹⁶⁴

What the panel did not do, and I find this very disappointing, is make sense of the last phrase of Article 30, taking into account all of the three-step test, but then considering the legitimate interests of third parties. Who are these third parties? Would that be, for example, governments in developing countries who are under an obligation? Or, as I will show in the South African case, a constitutional obligation to provide affordable medicine to their citizens? The ruling provides no guidance on that.

The question, I think, would be if you looked at Section 15(c) of the South African Patents Act¹⁶⁵ and you test that against the interpretation of Article 30 of the TRIPS Agreement in the *Canadian Pharmaceuticals* case,¹⁶⁶ and determine whether that would then fall foul of Article 30. I think it would. I think if you look purely at the wide-ranging terminology of Section 15(c), it is not in compliance with Article 30 of the TRIPS Agreement.

What is also important, I think, when we look at Section 15(c), is to look at the constitutional context within which the South African Government operates in this respect, because it will be the constitutional context you will find in many developing countries, as emerging democracies, when they adopt constitutions, and also bills of rights which give effect to the socioeconomic rights in the Declaration of 1961.¹⁶⁷

There are two sections in the Bill of Rights in the South African Constitution that are important here.¹⁶⁸ The first one, and this is the

¹⁶⁴ *Id.*

¹⁶⁵ Section 15(c) of South African Medicines and Related Substances Control Act No. 101 of 1965.

¹⁶⁶ See TRIPS Art. 30, *supra* note 16; *Canadian Pharmaceutical Case*, *supra* note 156.

¹⁶⁷ In 1960 the government of South Africa held a referendum to decide whether South Africa would become a Republic. On May 31, 1961 South Africa was declared a Republic. See Declaration of the Republic of South Africa, May 31, 1961.

¹⁶⁸ Constitution of the Republic of South Africa, Act 108 of 1996 §§ 7-39 (Bill of Rights).

one on which, of course, the Pharmaceutical Manufacturers Association relied, is the protection of property.¹⁶⁹

Section 25 of the Constitution states, “No one may be deprived of property except in terms of laws of general application, and no law may permit arbitrary deprivation of property.”¹⁷⁰ Then it continues, in Subsection 2, “Property may be expropriated only in terms of law of general application for a public purpose or in the public interest and subject to compensation.”¹⁷¹ So you cannot expropriate and not pay. For example, the argument here would also be since the Constitutional Court has ruled that property includes intellectual property, it cannot do anything which amounts to an expropriation of intellectual property without payment of compensation.

The second horn of the dilemma, then, is the protection of the socioeconomic rights in Section 27 of the Bill of Rights, which says that everyone has the right to have access to health care services.¹⁷² It is a broad statement. And then, a constitutional obligation on the State, “The State must take reasonable legislative and other measures within its available resources to achieve the progressive realization of this right.”¹⁷³

That, of course, was the problem of the Department of Health in South Africa.¹⁷⁴ On the one hand, it is forced to give effect to the protection of property in Section 27; on the other hand, it has a constitutional obligation to its citizens to provide health care services and it must take legislative measures to do so and, of course, other measures given its available resources.¹⁷⁵ That is the background to Section 15(c).¹⁷⁶ That is one of the legislative measures taken.

¹⁶⁹ Constitution of the Republic of South Africa, Act 108 of 1996 § 25 (Protection of Property).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² Constitution of the Republic of South Africa, Act 108 of 1996 § 27 (Health Care, Food, Water, and Social Security).

¹⁷³ *Id.*

¹⁷⁴ See General Information about the Department of Health of South Africa, available at <http://196.36.153.56/doh> (last visited Mar. 8, 2002).

¹⁷⁵ See *supra* note 172.

¹⁷⁶ Section 15(c) of South African Medicines and Related Substances Control Act No.

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The problem, of course, comes back to economics, that the expropriation of intellectual property rights or the curtailment of intellectual property rights here, in terms of the Constitution, has to be subject to the payment of compensation. The question is whether in developing countries there are the financial resources available to make sense of the possibility of these exceptions, or the availability of exceptions in international patent instruments.

Another possibility, of course—and this is the one that Jamie touched on, which is a process underway in South Africa—is the application for a compulsory license.¹⁷⁷ The TRIPS Agreement, of course, allows for compulsory licenses, and it also allows for compulsory licenses in the case of national emergencies.¹⁷⁸ There are frequent calls in South Africa these days for declaring HIV/AIDS a national emergency, which would allow the South African Government to override certain of its obligations in terms of the TRIPS Agreement.¹⁷⁹ It also would bring special provisions relating to compulsory licenses into play.

The important thing to note again is that a compulsory license presupposes the existence of certain conditions. It presupposes that there will be compensation payable to the patent owner, which again is a question of economics, given the sort of limited budgets and limited financial resources of these governments. It also presupposes to a large extent the existence of a national industry to actually manufacture these drugs in terms of a compulsory license, which is a reality in South Africa, but is unfortunately not the reality for most of the developing countries.

Thank you, Mr. Chairman. That is my introduction.

MR. WARNER: Thanks.

101 of 1965.

¹⁷⁷ See remarks of James Love, *supra* notes 48-100 and accompanying text.

¹⁷⁸ See *TRIPS*, *supra* note 16.

¹⁷⁹ See, e.g., Brazilian Generic Drugs in South Africa: The Background, Medecins Sans Frontieres, Campaign for Access to Essential Medicines (Jan. 29, 2002), available at <http://www.accessmed-msf.org/prod/publications.asp?scentid=29120021037154&contenttype=PARA&> (advocating a change in policy of South Africa on importing AIDS drugs).

Moving down the line, we will conclude with PhRMA, and then I think we will get into a very good discussion, based on what we have heard so far.

MS. FINSTON: My name is Susan Kling Finston, I am from PhRMA, and I will give the PhRMA presentation.

I first want to thank the *Fordham Intellectual Property, Media & Entertainment Law Journal* for inviting me today. My first option was to be in Beirut, and let's hope I made the right choice.

Second, I think there has already been a lot of discussion of what you would think of as the typical PhRMA overview. Jamie has alluded to safety and also to the antiretroviral patent issue; we have heard a lot about a number of issues.

You have my full presentation in the handout, in the soft-cover one. I would invite you to look at it. I am not going to go over the whole thing because I very much want to stay within my time limit. I want to make sure we have a lot of time for questions. That is usually the more interesting part. If there is anything that I do not cover that you would like to hear more about, you can ask me about it during the Q&A and I would be happy to give more detail.

[Slide] If you do not know who PhRMA is, you can read that.

I want to talk about some of the positive elements of what patents bring, because that has kind of gotten lost in the shuffle. There is a reason why there is a social contract that relates patents to publication or disclosure of discovery.

[Slide] There is no such thing as a monopoly with a patent, but there is an exclusive right to an idea. That exists before the patent is issued. What causes someone to disclose the idea for the benefit of mankind is the whole idea of a patent, and that is something we have not really talked about.

[Slide] In addition, trademarks are very important consumer protection articles, and the trademark is the only form of intellectual property law that is actually designed to indicate to the consumer what they are getting. In developing countries, that is very important because they do not have the FDA or the European Agency for the

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Evaluation of Medicinal Products, and they really need those consumer protections. Before going on to those elements, though, I want to go a little farther into the issue of the patents. We have talked about HIV/AIDS therapies, but I want to talk about other leading causes of death.

[Slide] Malaria kills a million people worldwide every year.¹⁸⁰ From the PhRMA Survey of Data, which is I believe also inserted into the hard cover of the record, a little more than 4 percent of the drugs are patented throughout sub-Saharan Africa, the same subset of countries.¹⁸¹

[Slide] For opportunistic infection drugs, it is even lower.¹⁸² And, as we have heard from Pfizer, there is a full five-year offer for Diflucan at no cost.¹⁸³ So that basically should make the patent irrelevant, as long as countries are willing to register the drug and to distribute it, because there is no cost to them to get the drug.

[Slide] For tuberculosis drugs, it is only 0.5 percent.¹⁸⁴ And again, our companies, with the help of WHO and MSF, have entered into an agreement so that those patents become irrelevant because they are being donated.

[Slide] The same thing is true for trypanosomiasis, sleeping sickness; there are zero patents.¹⁸⁵ And for diarrheal disease, zero patents.¹⁸⁶ Diarrheal disease is particularly tragic because 2 million

¹⁸⁰ See Roger Bate & Richard Tren, *TRIPS and Healthcare: Rethinking the Debate—Malaria and Patents*, *International Policy Network* (2001), available at <http://www.policynetwork.net/Iphealth>.

¹⁸¹ Susan Kling Finston is referring to a slide entitled Myth vs. Reality: The Absence of Patents in Africa, which states that 4.35% of Malaria drugs were patented as of October, 2001.

¹⁸² *Id.* (stating that 2.51% of drugs for opportunistic infections were patented as of October 2001).

¹⁸³ See remarks of Robert Mallett, *supra* notes 20-47 and accompanying text.

¹⁸⁴ Susan Kling Finston is referring to a slide entitled Myth vs. Reality: The Absence of Patents in Africa, which states that .51% of tuberculosis drugs were patented as of October 2001.

¹⁸⁵ *Id.* (stating that 0% of trypanosomiasis drugs were patented as of October 2001).

¹⁸⁶ *Id.* (stating that 0% of drugs used to treat diarrheal were patented as of October 2001).

people die a year from it worldwide,¹⁸⁷ many of them babies or children, and the treatment requires potable water, but it is very, very cheap, and we cannot even deliver that.

As Dr. Kenneth Ofosu-Barko of the UNAIDS Mission in Zambia said, it is not just HIV/AIDS, it is the whole health care infrastructure.¹⁸⁸ It is flat on its back. And so, I think it is important, specifically when you talk about HIV/AIDS deaths, to realize that one-third of those deaths are actually due to tuberculosis, and these people have all kinds of cross-infections, and we have to be able to look at the whole picture and deal with that.

[Slide] We have talked about some other factors. But I would like to spend most of my time talking about the positive benefits, because I think it is important not to take any negative steps that can make the access situation much more complicated and worse. There are two elements that are generally discussed. I know that Jamie is not particularly associated with these things, but they tend to be the NGO positions on what should happen in the next negotiating round.

We have talked a lot about expanding efforts for concessionary prices, donations, other cooperative efforts. When we talk about compulsory licensing, it is usually well understood that we are talking about a market failure. In this situation, we actually have a market that is improving access. We have, in fact, recently notified voluntary licenses to Aspen Care, a generic company in South Africa, that has gotten now the rights to produce BMS products, SKB products, Merck products.¹⁸⁹ That shows that even where there are patents in South Africa, the patents do not have to be a barrier if there is a market, and that is what is going on.

¹⁸⁷ See, e.g., Reducing Deaths Due to Diarrhea, Section 5, available at www.basics.org/pdf/worldsummit/worldsummit_sec5.pdf (stating that the annual number of deaths attributed to diarrhea worldwide declined from 3.3 million in 1990 to 1.5 million in 1999).

¹⁸⁸ UNAIDS/WHO Report on Health Reform and HIV Workshop: An Agenda for Health Reform and HIV, June 26-28, 1998, available at wbweb4.worldbank.org/database/reprohealth/m2s9unaid.pdf.

¹⁸⁹ See, e.g., Dr. Appaji's Notes: New Developments—GlaxoSmithKline Licenses Production of Generic AIDS Drugs in SA, Pharmabiz.com, Oct. 17, 2001, available at <http://www.pharmabiz.com/appa/appa35.asp>.

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Compulsory licensing, as Jamie and others have said, is a measure included in the TRIPS Agreement.¹⁹⁰ We just do not believe—and governments have taken this position as well—that it is in developing countries' best interest. It does not promote technology transfer. Ultimately it has not been shown to promote access. It has become a solution looking for a problem. But when your only tool is a hammer, everything looks like a nail.

[Slide] The second issue, parallel importation,¹⁹¹ is actually quite different, because it is downright dangerous. It creates serious risks to the public from counterfeit or substandard medicines, and that is why two successive secretaries of HHS have refused to implement it. But this would put in developing countries, where there is greater risk from counterfeits, a standard that we are not willing to accept for ourselves.

And equally importantly, it has a history of diverting low-priced medicines from the markets where they are intended, and the recipients, the beneficiaries, tend to be OECD countries where they can purchase the low-cost medicine.

[Slide] But because it breaks the integrity of the supply chain, counterfeits will penetrate the supply chain. This has been demonstrated over and over again in many countries. Now, the interesting thing is that even experts cannot really tell all of these different kinds of counterfeit products apart. I am going to show you a product that is an actual copy, a counterfeit, of 3TC. It was picked up in Hong Kong. If you look at the two bottles, it is very difficult to tell them apart.¹⁹² The counterfeiters were even able, to a certain extent, to reproduce some of the anti-counterfeiting features. However, there is a single difference: there is no active ingredient in the counterfeit, none whatsoever.

¹⁹⁰ See *TRIPS*, *supra* note 16.

¹⁹¹ Parallel imports are trademarked or patented goods that are sold by the right owner in one country for export to a second country but are purchased in the second country and exported into a third country without the consent of the patent or trademark owner. Parallel Importation of Pharmaceuticals, PhRMA, available at <http://www.phrma.org/intnatl/intellprop/parallel.phtml> (last visited Mar. 8, 2002).

¹⁹² Susan Kling Finston is referring to a slide entitled Counterfeit HIV/AIDS Drugs, which depicts seemingly identical packages of 3TC, an antiviral for HIV.

[Slide] These are just a number of the articles that have appeared recently.¹⁹³ I have left off the really celebrated case in the last couple of years where 500 people died in developing countries because of cough medicine that was tainted with glycol.¹⁹⁴ That was just tragic.

This is the kind of thing that we are talking about in developing countries, because if the product is not trademarked, if it is not patented, there is a huge opportunity for lowered IP leading to threatened health and safety.

Now, one of the key issues is bioequivalence.¹⁹⁵ The Cipla product that Jamie was holding up today, as far as I am aware, has not been through bioequivalence. It is, in a sense, a clinical study on the people of Africa. That is unacceptable to PhRMA members. The other issues also are very important, because there is no communication with the manufacturer when you have parallel importation. It is impossible to maintain stocks or have recalls. These are very important issues.

[Slide] Let's look at this example. I believe it is Ponstan.¹⁹⁶ If you look at the bottom slide, it looks identical to what would be a legitimate product. If you look at the top slide, unfortunately it is made from highway paint and boric acid, which is an insecticide. Very dangerous stuff.

¹⁹³ Susan Kling Finston is referring to a slide entitled *The Global Threat of Counterfeits: Media Regularly Report the Horror Stories from the U.S. and Overseas*. The slide cites *FDA Requests Ban on Drug Imports*, HARTFORD COURANT, June 8, 2001; *3 Fake Drugs are Found in Pharmacies*, N.Y. TIMES, June 5, 2001; *Dozens Dead in Cambodia From Counterfeit Drugs*, United Nations Foundation, UNWIRE, May 30, 2000; *More Substandard Medicines Spread in Worldwide Traffic*, AGENCE FRANCE PRESSE, May 19, 2000.

¹⁹⁴ See World Health Organization Bulletin, *Lethal Medicine*, Feb. 7, 2001, available at [http://www.who.int/bulletin/Thismonth/february.htm#Lethal medicine](http://www.who.int/bulletin/Thismonth/february.htm#Lethal%20medicine) (noting that over the past two decades, several hundred people, mostly children, in many countries are known to have died from renal failure after ingesting medicines containing diethylene glycol, a common constituent of motor vehicle anti-freeze).

¹⁹⁵ Bioequivalence has been defined by the U.S. Food and Drug Administration as pharmaceutical equivalents whose rate and extent of absorption are not statistically different when administered to patients or subjects at the same molar dose under similar experimental conditions. FDA Definition of Bioequivalence, available at www.fda.gov/ohrms/dockets/ac/01/slides/3764s1_01_connor/sld002.htm.

¹⁹⁶ Susan Kling Finston is referring to a slide on which Ponstan, a drug used to treat menstrual pain, is depicted along with a counterfeit composed of boric acid, floor wax, and yellow leaded highway paint.

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These are all products that were picked up in markets already.

WHO actually says that developing countries are at greatest risk.¹⁹⁷ We will not do it in our country, but developing countries have 65 percent of all reported counterfeiting.¹⁹⁸ In only 7 percent of the cases was there even an appropriate level of active ingredient.¹⁹⁹

We have real dangers from ineffective sub- or super-potent medicines.

[Slide] In the HIV/AIDS area, I want to point out this is particularly dangerous because we have a limited number of therapies. We do not have a cure. Kenya has adopted an IP law and there are now clinical trials going on there.²⁰⁰ That is one of the values of IP. They are getting the technology transfer. The research is going on there. In the absence of IP laws, it could not. But we are not there yet. We cannot use up the cures. We cannot have poor patient compliance. We cannot have an inability to recall these dangerous medicines, and the adverse reactions or shortages. It is really critical.

[Slide] I want to show you as one of my last slides an actual counterfeit manufacturing site. I do not think it is sterile. What we have is the law of unintended consequences. We have actually been there before, and we have an example in a developing country.

In the 1990s Kenya first adopted parallel importation without the compulsory licensing provisions that they have now, but just the parallel importation.²⁰¹ They were flooded with counterfeit

¹⁹⁷ See World Health Organization Press Release, *Combating Counterfeit Drugs: A Shared Responsibility*, WHO/84, Nov. 28, 1997, available at <http://old.healthnet.org/programs/e-drug-hma/e-drug.199712/msg00019.html> (stating that 65% of counterfeit drug cases occurred in developing countries between 1982 and 1997).

¹⁹⁸ *Id.*

¹⁹⁹ *Id.* (noting that the majority of counterfeit drugs reported contained less active material ingredient than claimed, wrong ingredients, or no ingredient at all, which makes them less effective or even toxic).

²⁰⁰ See Kenya-AIDS Vaccine: Clinical Trials of First AIDS Vaccine to Begin in Kenya, AGENCE FRANCE-PRESSE, Dec. 19, 2000, available at <http://www.aegis.com/news/afp/2000/AF0012B7.html>.

²⁰¹ See Pharmaceutical Industry Profile 2001, Global Intellectual Property Protection, PhRMA, available at <http://www.phrma.org/publications/publications/profile01/chapter8>.

medicines that overwhelmed their legal system and their boundaries. They repealed it in 1997.²⁰² Under tremendous NGO pressure, they adopted new compulsory licensing and parallel importation provisions that were supposed to improve access.²⁰³ To the contrary, within months the government again declared a public health crisis.²⁰⁴ Lowering intellectual property rights is not the answer, but can actually make the problem worse.

In Nigeria, where there is a plan to import Cipla products, they already, according to a *Lancet* study from last year, have a 43 percent rate of counterfeits or sub-standard medicines in pharmacies in the two major cities—not out in the bush or on the street at vendors—but in Abuja, the capital, and in Lagos, the largest commercial center, forty-three percent of the medicines sampled out of legal pharmacies, where as a tourist you might go to purchase something if you were there, turned out to be sub-potent or counterfeit.²⁰⁵ To me that is a pretty scary statistic. I would think that would scare anyone.

Lower IP standards become a target of opportunity for organized crime and terrorists. I was at a conference on Monday. I was shocked to find out that there are actually documented cases of terrorists in the Middle East—fortunately, not the World Trade Center issue—but Hezbollah was able to raise money in the United States by setting up fake fronts for charities, getting donations from PhRMA members, and then diverting them to the black market. God knows how they handled them or what ultimately happened, because this is all just information we are finding out now. But they used that money to fund their terrorist activities.

phtml#intellectual (last visited Mar. 8, 2002) (“In the 1990s, the Government of Kenya experimented with parallel importation, but terminated the practice in 1997 when it was recognized that the policy had caused dangerous counterfeit medicines to flood the market, imperiling its citizens with no demonstrable savings to the Government. Unfortunately, with recent passage of a largely TRIPS-consistent legislation, Kenya again appears to be considering parallel importation.”).

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ See Sarah Boseley, *Fake Medicines Threaten Poor*, GUARDIAN, June 16, 2001, available at <http://www.guardian.co.uk/aids/story/0,7369,507755,00.html> (citing *Lancet* report that large amounts of fake and substandard drugs are being sold through bona fide distributors in Nigeria).

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[Slide] PhRMA has been contacted by the Office of Homeland Security. We have set up a Bioterrorism Task Force.²⁰⁶ We are going to work with the FDA on a new counterfeit Working Group. I want to let you know that we are keeping our vigilance up at this very sensitive time.

Public safety should come first, and that is very important in the ARV area because not only can it not help the people in Africa, it can lead to faster resistance for the limited number of cures we have. We should not take actions that are shortsighted and make the problem worse.

That is not to say that I am satisfied with the contribution yet of the industry, which is coming along, but it still can do more. Nor is that to say that OECD countries can privatize this issue. The pharmaceutical industry, as Amir pointed out eloquently, is a part of the problem.²⁰⁷ We are an important part of the problem. But this cannot be privatized and laid at one industry's door. Developed countries must take the responsibility to provide the financing, the capacity, and help with the infrastructure.

Our companies, since 1998, have given \$1.9 billion both in medicines and in capacity-building assistance. This is ongoing, and there has been a huge leap just in the last year. But our industry cannot do it alone, and I think that is a very good point that Amir made. And if we are held to that standard, we will all fail the people of Africa.

Thank you.

MR. WARNER: We are going to have a certain period here for questions, but I do not want to give Jamie a chance to rebut all of what was said here, because that could take a day or three. But Jamie, if you could have maybe a minute or two to either direct a question at someone here or answer something. I want to give the audience time to ask questions.

²⁰⁶ See PhRMA Scientific and Regulatory Affairs: Bioterrorism Information, available at <http://srpub.phrma.org/bwc.news.html>.

²⁰⁷ See remarks of Amir Attaran, *supra* notes 102-139 and accompanying text.

It seems to me we have three major lines where we can have a discussion. I do not know how many people here are really technicians where we can get into a debate about what is in the cocktail or what is not in the cocktail. Frankly, I do not know. It is an important issue, but I am not so sure we can settle that here.

But there are important issues about the financing. We have not gotten to the level of detail yet, but what does it mean in terms of taxation? Are we, the consumers in the United States—because that is really what it means—prepared to pay the price here, in our HMO or wherever, for these drugs? It is that level of detail we need to get down for funding. Or are we just going to tax back the profits of a corporation?

The funding issue, it is fine to address it, Amir, but we need to go one step further. As for the patent issue, are patents the problem? We have the difference between Amir and Jamie, and we ought to discuss that a little bit more.

And then, the third thing is this question about incentives. We have spent a lot of time discussing incentives. We need the patent laws to give us the appropriate incentives for research and development. If you say we want to deal with the incentives to investment, we can also lower the risks in another place.

I am just throwing this on the table. I am not advocating any of this.

It seems to me those are the three lines where we could profitably have a discussion.

But, Jamie, let me give you about two minutes or so to either make a point or ask a question, because I do not think you will have time to rebut everything, but sort of focus questions on your colleagues.

MR. LOVE: Well, the first thing I would like to bring up is that when Amir made this reference that I was incorrect, and suggested that you needed 3TC in a regime—what I was saying was that if you are going to treat AIDS patients in Africa and you really wanted to help the AIDS patients in Africa, the kind of drugs that you would want to have, given the cheapest ones to manufacture and the ones

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that have the best compliance regimes, the ones that are involved in three-in-one, that work better with dietary restrictions and things like that, according to the people on the ground, according to Medecins Sans Frontieres, Richard Jeffreys, Oxfam, people like that, and even reflected in many respects in the U.K. treatment guidelines, are products that are really heavily blocked.

I mean, sure, if Amir wants to go through the thirty combinations and pick out five that he thinks he wants to present at this meeting and ignore the others and give kind of a biased version of what the nature of the problem is, he can do it. You know, you would have to spend a lot of time figuring out whom you trust on this. I cannot really waste the rest of your afternoon on this issue.

But I would just say that it is an area that certainly our groups think is completely wrong, and that all the people on the ground think that, for cost reasons, for compliance reasons, and because also the better versions of all these older drugs are always coming out under patent too, that this is a big problem.

Number two, I think it is pretty clear there was no link made between why higher prices on drugs somehow gets you funding for the health care infrastructure. I mean, it is a terrible problem, the problem in Africa. I think, even before Harvard discovered through Amir's research that people in Africa were poor, a lot of people understood that.

I think that it has been a little hard for us in the field to understand how somehow paying top dollar for drugs is somehow making the poor rich by itself. So we know that it has always been the case when the drug companies promote their standard campaign in most of the world: The problem is not price, it is getting somebody to pay that price. It is because the market failure is that people do not have enough to pay for our products. I mean, that is kind of one way to say it, and it is true. It is a shame. I feel bad for PhRMA that people do not have enough money to pay for their products. But it is also bad for the person who does not have the money. And there is more than one way to do it. So it is one thing to raise the funding issue, like you really care about the poor. It is another thing to sort of make

a connection between people being poor and wanting to pay higher prices.

The last things I will mention are the quality issue and the R&D thing. Intellectual Property Rights (“IPRs”) are not a mechanism to ensure quality. Governments have regulatory systems which are designed to do that. Nobody who gets authorization to use a patent in South Africa can do it unless they register the drug with the South African Government, which has one of the best regulatory systems in the world. In fact, it is so good, the U.S. recognizes this as one of the areas that they would consider a quality registration system. But whatever the registration system is, that is a regulatory issue, and as to whether there is a patent or not, that is a separate issue.

Brands play a part in that. If Glaxo thinks it has a good reputation for quality—and they have an above-average reputation for quality—that is why they have such high penetration in Africa, because people do not trust a lot of generic brands. So the quality issue is a big thing.

But I also mentioned these guys are also blocking every effort to get the WHO to move forward and actually solve the problem. One of the things we have asked is to be able to register the products prior to the patent expiration in the United States and Europe, which is illegal now, for all these products.

So the quality issue is important, but it is not an excuse not to overcome the patent barrier. And on the R&D thing, the proposal that we have pushed, really since 1994 internationally, beginning in Argentina and at a whole series of international meetings, is to push the trading system toward an agreement about research and development.

We do not think the point of the treaty system is to protect property owners per se. It is to promote innovation and promote research and development. And you do it different ways. I mean, you can have public funding, like we do at NIH.²⁰⁸ You can have mandatory obligations that companies do research, which some

²⁰⁸ See Information about the National Institute of Health, available at <http://www.nih.gov>.

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countries do and the United States toys with in certain areas. Or you can have private property rights, which pay for R&D through high prices, like we do in the United States. Any of these things are possible.

So we think the treaty should be on research and development—like the G8 negotiations in funding tropical diseases, or the Blair-Clinton agreement on sequencing the human genome, and things like that—and less on property rights, because we think it is unethical to push a single model to fund IPR which is literally killing and creating enormous suffering and resentment toward Americans.

I mean, if you want to know why people do not like Americans, it is because they think it is really quite unfair to use our power and to link exports to our country and our trade policy and things like that, and the OGA certification in Africa right now, to access to medicine, when they personally know people who are going through this.

Think about how it must be perceived outside of the United States as you leave the corporate center of Manhattan, and then think about whether that is the way you want to advertise yourself on a continent that only represents 1 percent of the global pharmaceutical market anyhow.

MR. WARNER: Thank you, Jamie.

At the end we will have a chance for the panelists to make comments, but I wanted to take that and go to your questions to all of us because I think a lot of the issues will come out through your questions. If you do not have any, then we will go back to sparring.

Please identify yourself

QUESTIONER: Jeff Kemprecos from Merck & Company.

My question goes to Jamie. We have just been doing some research focusing on the antiretrovirals. There is a whole host of products, the drugs used in opportunistic infection, about three dozen products, which if they were available to people in Africa and other developing countries would make a huge difference in their daily lives. We could treat things like Kaposi's sarcoma and other things. Most of those drugs are off-patent in the United States, so that is a

pretty good surrogate marker for Africa. We find the rates in Africa in our preliminary research are fractional.

My question is this: if patents are blocking access and we cannot find any patents, what is the story here? And what is the generic industry doing to get those products to people?

And finally, we have been told that India is the patent-free Nirvana. 24,000 companies, we are told, many of them making antiretrovirals. India has a huge caseload of HIV. We are talking now maybe some half-a-million people who need treatment today, maybe a million people, and yet we are only able to count a few thousand people who have access.

So India, the opportunistic infection drugs, what is the explanation? It seems to me it just cannot be patents, but perhaps you have another view.

MR. LOVE: I think it is quite important, because there is this sort of Holy Grail for the people in the issue of access to medicine. If anybody actually can identify *the* problem, I would appreciate it if they would let us know, because it is sort of elusive to us. What we see is a whole lot of different problems.

I think that the Merck comment is also dead on. I mean, there are massive problems in products that are off-patent. There is even irrational pricing in the United States. In drug stores here, you can pay fifty times the cost on a generic product for no reason at all; you just get ripped off at the pharmacy. And you have inefficient distribution. You have lack of funding.

India has more AIDS patients, I believe, than South Africa does, and the government does nothing really to deal with it.

So if you start running through the list of problems, I think in some ways—I offered to write a paper with Harvey Bale from the International Federation of Pharmaceutical Manufacturers Association—once to say it is not all their fault, where we would list areas of consensus, and I would defend the honor of the drug companies in areas that I thought it was not completely wrong—and I have made that offer on numerous occasions. I think they think

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they would get fired if they ever co-authored anything with me, so they have kind of shied away from that. But I thought it would have been a good trick, because I am not perceived to be a shill for the industry, and I thought that could be useful to them.

And I am happy to do it actually, because I agree with you that it is not all the companies' fault, and I think we want a strong pharmaceutical industry. We want a strong branded, research-based pharmaceutical industry, and we want their innovations and we want their investments, and nobody is trying to destroy that.

On the other hand, we wade into an issue and we see problems, and if there are some problems—whether it is 1 percent, 5 percent, 50 percent, or 13.5 percent—we want that problem fixed, just like we want all the other problems fixed, and we are not going to fix them all. It is Africa and it is a bad situation. I think that if the expectation is you do everything right, that should not be an excuse to do nothing.

MR. WARNER: Amir, did you want to comment on that question?

MR. ATTARAN: Wow. I certainly have been given a lot on my plate. I will try to be a bit more concise than that and make my points.

Jamie levies the criticism of the selection of antiretroviral regimens, and that what we published is somehow not representative. Jamie contends that it is really the wrong regimens that I have analyzed, and that really, if you look at the right ones, then patents are a very large barrier indeed. He points out that some regimens are easier to take than others and so forth.

He mentions, for instance, the one-pill combinations. Now, nobody doubts that a one-pill combination would be a very nice thing, but here is the reality. I must turn to Jamie's own statement on this, "you have to decide whom you trust on this." That is exactly what he said.

We did this analysis. We published it as a lead article in a peer-reviewed journal, the *Journal of the American Medical*

Association.²⁰⁹ We did the analysis through the lens of the Treatment Recommendation Guidelines of the Department of Health and Human Services. I am an immunologist. I consulted extensively with colleagues at Harvard who do AIDS treatment. And Jamie tells me that it is all wrong.

MR. LOVE: Not only me.

MR. ATTARAN: And so I agree, you have to decide whom you trust on this.

What I can say is, of the one-pill combinations that are available, two of the three contain Nevirapine, which is a drug that is not “strongly recommended” by the Department of Health and Human Services. It does not make that list. And the third one is a very new drug that has very little clinical experience. It probably will prove to be excellent, but we do not know that at the present time.

Jamie then mentions that my argument was that higher prices on drugs will be good for the poor and will attract international aid. That is not what I said.

What I said is that the absence of international aid right now presents a fatal, total, undeniable impasse to treatment. I can infer no causation between prices and the amount of international aid that a country brings in from the rich countries. I think there is no connection, although Jamie suggests there is.

In considering the question of the relative contribution of patents and finance to the impasse of treatment right now. What I can say is that, hypothetically, if I could wave a magic wand, and with that wave I have made to disappear every patent from the face of the earth [waves]. They are all gone. I do not think that treatment access in the poorest countries will change very much, and I will give you two reasons for that.

First of all is the case of India. India is where almost all of these generics Jamie is talking about are being manufactured. Someone wanting to use a generic drug in India faces the lowest possible

²⁰⁹ *Attaran & Gillespie-White, supra* note 80.

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transaction cost for acquiring that drug, because there is no import/export, you are just doing it in the country.

Jamie said he thinks India has more AIDS patients than South Africa. Actually it has slightly less, but it is quite close, about the same. Both have about 4 million HIV-positive people.

Well, today, right now, in India none of those cheap, low-transaction-cost drugs for those AIDS patients, none of them are patented, because India has not had the laws to do that—or perhaps one or two of the most recent drugs out of about twenty are patented—but, probably zero, because they have not had the laws that allowed those drugs to be patented. And in India nobody is getting treated right now, hardly anyone—maybe a few tens of thousands.

So here you have a situation, a natural experiment, you have essentially lots of patients needing treatment, unsatiated demand for treatment, no patents, local manufacture for generics, and you still are not getting treatment. Why? Because something downstream on the chain that I showed you, downstream of patents and competition, is a fatal barrier, and that is the lack of finance.

The point is that we are actually in agreement on the finance issue. Where we are in disagreement is Jamie thinks that the patent issue is an enormous barrier. I think it is a modest one. I am not saying it is zero. I have never said that patents cannot matter to public health. Certainly, absolutely, positively they can, absolutely. But in the circumstance of antiretroviral drugs in Africa in 2001, for which we have I think very-near-flawless data, we do not have the evidence of that.

MR. WARNER: Okay. Amir, I want to turn to questions.

On the funding, because I think, in all fairness, we have to say that it has been about forty years that all of the OECD members have been saying that they are going to get 0.7 percent of their GDP. And we are far from that.

MR. ATTARAN: Five OECD countries are meeting it, but most are not. The United States is last, the least generous country.

MR. WARNER: The point is I do not think we are even close to it.

In terms of the money that is pledged so far in the Secretary General's initiative, very little of that has actually been collected.

We can talk about your point about patents and funding, but in this world, where we are now dropping trillion-dollar bombs on ten-dollar tents, or whatever it is, the reality is I do not know where that money is coming from to purchase these drugs.

But let's go to your questions.

QUESTIONER: My name is Jenny McGill.

A question about the case of Brazil. Perhaps the panelists, with their different points of view, could comment on why Brazil has been so successful. It has nothing to do with the examples that you were talking about.

MR. WARNER: Let's start with Susan.

MS. FINSTON: Brazil is a very good example of everything coming together. It starts at the top. They have tremendous political will. They have been willing to talk openly and have dialogue about very difficult cultural taboos. They have had political will for education campaigns, for prevention campaigns.

This is not to say that prevention is the answer, but it is part of the solution, because you cannot treat everyone in your country, and the only way that treatment ever can become affordable is if the rate of retransmission is brought down to a number less than one and approaching zero. I am not sure what the retransmission rate in Brazil is right now, but they have had a public campaign that has been very successful on prevention.

They have made universal access to treatment a very important part of the program. Because, as Jamie pointed out, they were an early comer to patent law, they attracted, from 1996 to 2000, \$2 billion in technology transfer and investment in their chemicals and pharmaceuticals sector, so their generic sector has really been bulked

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up.²¹⁰ They are now able to produce slightly more than 19 percent of the products locally, and they are producing them completely consistently with their international obligations under TRIPS, and this has all been part of their overall campaign.

They have, from time to time, used compulsory licensing as a bargaining chip, and when it has come up, that has been PhRMA's comment. We think that there are ongoing negotiations. We think that this will probably result in a meeting of the minds.

And there has not ultimately been any market failure, and they have been able to get very good prices internationally competitively, by pitting products and therapeutic categories against each other. That is something that other governments have not tried to lower prices, and that is a kind of market competition, because we have a number of products within therapeutic classes that if government were interested in competition to lower prices, could be done even for patented products. That really has not been tried. So when we talk about market failure, number one, we have not had it; but, number two, the competition actually has never even been tried.

I know others will want to add, but those are, I think, some of the salient factors in why Brazil has reached about 50 percent of the population that needs treatment. That is the highest number we have anywhere in the world. That shows you how difficult it is to reach 100 percent, even with the most committed government.

MR. WARNER: Robert? I will ask all our panelists to keep their responses short.

MR. MALLETT: I think what Susan said was quite right. They had a multi-prong approach to dealing with the disease.

The Brazilians claim to have a universal health care system, and it is in fact universal. It is universal if you want AIDS treatment. It is not universal for everything else, so lots of people still pay out-of-pocket for a number of drugs for other kinds of illnesses. But they have taken a very aggressive approach to dealing with HIV/AIDS.

²¹⁰ See remarks of James Love, *supra* notes 20-47 and accompanying text.

And they have used the threat of compulsory licenses to drive down the cost of a number of drugs. One of those drugs is Viracept, a patented product by Pfizer.²¹¹ It is not marketed outside of the United States by Pfizer, but by Roche.²¹² They were able to drive down the cost of that drug, quite obviously. Roche and the Brazilian Government participated in an arm's-length negotiation for them to get that drug.

They are to some extent solving their AIDS problem, but they still have an incredible number of problems around a number of other illnesses.

MR. WARNER: Amir, a quick response?

MR. ATTARAN: I just need to add one statistic to that. Ms. McGill, this was an outstanding question, and I think it proves the point that I have been making, that money has a large part to do with it.

Brazil has a GDP per capita of \$4,500 per year, roughly, wealth per head. Mozambique has \$150.²¹³ The difference is thirty-fold roughly between Brazil and Mozambique. Each person in Brazil is as rich as thirty Mozambicans. Mozambique has, at the same time, forty times the HIV positivity rate of Brazil. Imagine you are one-thirtieth as rich as Brazil and you have forty times as much AIDS. And that is the difference.

MR. WARNER: Let's let Jamie have his say on that.

MR. LOVE: In fact, there have been big disputes in two countries very similar to what Amir described. Thailand, which has a large

²¹¹ Nelfinavir (Pfizer's Viracept) is one of a class of anti-HIV drugs called protease inhibitors. These drugs work by blocking a part of HIV called protease. When protease is blocked, HIV makes copies of itself that cannot infect new cells. Protease inhibitors are almost always used in combination with at least two other anti-HIV drugs. See Information about Viracept, available at <http://www.viracept.com>.

²¹² See *Roche May Strike Deal with Brazil Over AIDS Drug Price*, REUTERS (Aug. 27, 2001), available at <http://www.hivandhepatitis.com/recent/pricing/082701f.htm> (discussing negotiation between Roche and the Brazilian government).

²¹³ See World Bank Report: Total GDP 2000, available at <http://www.worldbank.org/data/databytopic/GDP.pdf> (stating that Brazil's total GDP for the year 2000 was \$587,553 million, while Mozambique's GDP was \$3,812 million).

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AIDS population but a relatively manageable infection rate, and, to some degree, Brazil are similar cases.

In the Brazil issue, it is not what Susan said about them being early to adopt patent laws. I mean, the reason they could do it is because they adopted late, they adopted in 1996, so all the pre-1996 drugs were generic drugs there.

The key thing in Brazil is the social movement, or the patient movement. They have a strong social movement. No place is getting treatment without a strong patient movement from the infected people basically, number one. That is what pushed the government. It is very strong in Brazil.

Now, to talk about Amir's presentation, an interesting case on the Roche thing is that the Minister of Health said they were spending 28 percent of their whole drug purchases on AIDS on one drug, which was Viracept, because Roche was being a jerk and they were just charging the European price in Brazil. Now, he said that they could not continue the AIDS program in Brazil if they could not bring that price down, that it was just going to eat them alive.

What has happened is they started out using drugs with, I think, probably pretty shoddy regulatory controls on quality. This is another perspective on what Amir said. They cut the death rate in half. I mean, there may have been some quality problems in the drugs when they started out, but it did one thing that was pretty good, is it cut the number of people who were dying of AIDS by 50 percent.

Now, that is a problem, because now they are alive, in the sense that you have to pay for continued drugs. That is always why in a cost/benefit analysis letting them die always works out pretty well, because if you keep them alive they require more treatment.

Now, to keep people on treatment they have to continue to drive down the price of products. For the drug companies the good news is it creates a bigger and bigger market for them, just like in the United States.

MR. WARNER: Okay. Let's get another question here.

QUESTIONER: There is something that I do not understand completely. Why are there patents in the first place, if there is no profit to make, if nobody can afford to pay for the medicine? Are the drug companies just waiting for outside money to come in and pay for the drugs, or are they using it as a means to prevent re-exportation to the United States, or what is the fundamental reason for that?

MR. ATTARAN: Part of it is logical and part of it is idiosyncratic. That is an excellent question.

What we saw in the Africa study is that in South Africa, where the zenith of patenting is, where you get a lot of patents, and—surprise, surprise—South Africa is the richest country on the continent. So that is where there is a prospect of selling some drug—there is a real market—that is where a person might want a monopoly.

Bear in mind that you pay something for each patent you get. You pay an additional application fee for each country, additional maintenance fees, and so forth. So there is a cost to the patent seeker in patenting everywhere in Africa. They will pick and choose their countries in which to patent according to which markets are lucrative and in which they can contemplate future sales. So that is why I think South Africa is covered.

And also, a second reason is that South Africa has the technological capacity that it could regionally become a manufacturer of drugs and export them elsewhere in Africa. That is less important because the fact that there is a center for production in India and the fact that the drugs are tiny pills and so inexpensive to ship does not make that economic rationale as compelling.

But what is important to recognize is that there is also a lot of variation between the companies. Merck patented, for instance, in one or two countries in Africa. And Glaxo patented in twenty or thirty. That is what I mean by idiosyncratic.

When I interviewed an unnamed person at Glaxo who provided these data and confirmed them for us as being the truth, I asked,

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“Why the devil did you do that? It is so different from most of the other companies. Why did you imagine that there was a market to be reaped in Burkina Faso?” His attitude was: “We fought hard for those patent laws so I am going to use them.” He is no longer at that firm. But that will have been a very expensive strategy for his company, with probably very little to show for it on the return side.

MR. WARNER: Jamie, a quick response.

MR. LOVE: It has been a fundamental part of our foreign policy to push even the poorest country on earth to have the highest level of intellectual property on medicine, and it has been for twenty years.

I had one discussion with Pfizer at the World Health Assembly two years ago about India. I said, “look, there are 700 million really poor people in India,” and I pulled out some asthma medicine. I said, “this is priced low enough, like a dollar a month, that somebody who lives in India can give their kid this asthma medicine like I give it to my son. I think that is a good system.” He looked at me and he said, “you know, there are 200 million middle-class people in India, and think what a market that is.”

MR. MALLET: You know, we can have a conversation about the value of capitalism. This panel was about patents blocking access to medicines in Africa. Now, I think the data that Amir showed is rather definitive about that question.

Now, we can argue about the marketing practices of pharmaceutical companies all day and all night. It is a legitimate business. We are in the business to discover and to sell medicines. That is what we do, and the world is better for it.

Now, the question for this panel is whether or not patents are blocking access to medicines. I think, by and large, that is not true in Africa, because even, Amir, when we donate medicines in Africa, even when we drop the price to almost zero, these medicines are still not getting to people. So I think the answer is quite clear.

MR. WARNER: I want to cut this line off.

MS. FINSTON: I would like to say one thing about India.

Two-thirds of the population of India has no access to allopathic medicine whatsoever, and I think Jamie is fundamentally misrepresenting that. A population the size of the European Union and the United States combined has no access to Western medicine. And they took the wrong turn in 1970 and they are fundamentally behind all of their neighbors that went the other way. And I do not buy India as a public health success because they do not have patents. I have heard Jamie say that before, and that is fundamentally in error.

MR. WARNER: Okay. Let's turn to another question from the audience. Let's keep it brief, please.

QUESTIONER: I have a question for Susan Finston. You said that we confer patent rights in exchange for discovery. Well, in the case of drugs like AZT, d4T, and DDI, which were invented by the government, should we transfer the same rights to those companies? These are among the actual drugs Amir refers to the ones that are more patented in Africa. AZT is one of them.

MS. FINSTON: I actually have data on that. We can take another question while I get it out. The relative share of research is an important issue, and I brought some things on that I would like to get.

MR. WARNER: Okay. Let us have another question?

QUESTIONER: Joe Gim from *Fordham IPLJ*.

This question cuts to the funding as being a potential solution. I know, Amir, you are a big fan of that.

MR. ATTARAN: Yes, I am.

QUESTIONER: If the funding is not used for the implementation, for example, as you had suggested, education, or even the infrastructure that is necessary to distribute the drugs, but in fact is used to purchase the drugs for distribution, depending on the sensitivity of the demand scale and technically the supply as well, the demand is obviously going to shoot up. And, depending on how sensitive it is, the price will also rise, to the point where a lot of those people—the OECD countries that are donating the money will

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actually be doing a funds transfer to the pharmaceutical industry and the actual number of people who are getting more drugs, outside of the infrastructure that you mentioned, which I think would be successful—but if it was used towards the purchase of the drugs, you may end up with spending 60 or 70 percent of that donation basically just into the drug companies' pockets in the face of excess demand.

MR. ATTARAN: Is that a question, and who is it directed to?

QUESTIONER: Amir.

MR. WARNER: Okay. Briefly, Amir.

MR. ATTARAN: I do not know what the question in that is, but let me just share my thoughts.

MR. MALLETT: The question is whether or not the Global Fund should pay for drugs so that more patients can use them, and if they pay for drugs, is that not lining the pockets of the people who manufacture them?

MR. ATTARAN: Well, certainly if you pay for drugs from the Global Fund and from the rich countries, there is going to be somebody having that as income, as revenue, for selling you the drugs.

MR. MALLETT: What a novel idea.

MR. ATTARAN: That is fairly indisputable.

QUESTIONER: I am not concerned about the revenue, but that the price will actually rise as a result.

MR. ATTARAN: Well, this is not necessarily true. I mean, it depends on what the economics are of increased production.

Now, in most cases, there is an economy to scale. I think Jamie certainly agrees with it, and I would think in this case there is an economy to scale. So as you increase the quantity that is demanded, producers are able to leverage the quantity and get greater efficiencies in manufacturing larger quantities, and prices actually drop.

That is not always the case. There are some things that as the demand increases price goes up because scaling is difficult to achieve. Gold is an example of that. But these pills are not gold.

I am no economist, but I think for the most part economists would treat this scenario with the belief that as quantities increased prices would go down. That has been the example with drugs for tuberculosis, childhood vaccination, and many, many, many generic drugs. I do not see any reason why this one would be at variance with that past pattern.

MR. WARNER Okay. One quick thing. Jamie, please be very brief in your response.

MR. LOVE: Let's take antiretrovirals. In the United States, as demand for antiretrovirals has gone up, the price has gone up on the drugs. The old drugs, like DDI, a government-funded drug that was mentioned earlier—there is a whole slug of things that got invented on the government's nickel for which the prices have gone up over time.

But one thing we know for sure is that if you have competitive procurement for drugs, you cannot do any worse than if you are doing it from just one company. I do not know what philosophy is giving exclusive rights somehow gives you the best price, but I think that if you have a competitive procurement, if the big pharmaceutical company wants to lowball everybody, then they that opportunity.

MR. WARNER: Let's go to Susan. You are going to respond to the question that was asked earlier.

MS. FINSTON: There was a 1993 study at Tufts University Center for the Study of Drug Development and Department of Pharmacology and Experimental Therapeutics.²¹⁴ It showed that the U.S. industry was the source of most new drugs in the United

²¹⁴ See The Pharmaceutical Industry is the Source for Over 90% of Drugs Approved for Use in the U.S., Stats & Facts, A Weekly Report from America's Pharmaceutical Companies, Vol. 5, July 2001, available at <http://www.phrma.org/updates/07092001/index.phtml> (citing the Tufts University for the Study of Drug Development and Department of Pharmacology and Experimental Therapeutics Study, which was published in the *Journal of Clinical Pharmacology*).

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States.²¹⁵ That means to say that the majority of new drugs were substantially as a result of industry research and not of government research.

From 1981 to 1990 industry was the source of more than 92 percent of the new drugs, government was the source of 1 percent. And also, in the year 2000 industry spent \$24 billion on biomedical research and development compared to \$16 billion from NIH.²¹⁶

Jamie and I also talked about this in March, and as we went back and forth, he agreed that the innovative-based industry was really a critical element in developing a lot of the new drugs and the majority of the new HIV/AIDS products.

In the meantime, in terms of competitive tendering, because, as I said, there are a number of products in each therapeutic class, you can have a competitive tender multi-year with patented products without violating any intellectual property rights, and that has never been tried.

MR. WARNER: Another question?

QUESTIONER: My name is Jason Schaeffer.

Ms. Finston addressed the issue of parallel imports, and the issue related to that, of course, is patent rights, whether national or international. It seems that the problem is a question of enforcement and then also a question of reimportation. I am also curious as to Pfizer's opinion on parallel importation and what results in that.

MR. MALLETT: I think Susan's presentation was quite effective in discussing why we are troubled by the movement towards more parallel importation. I think she was rather definitive, and that is the point of view that we have.

It would be a very difficult argument to make for a pharmaceutical company that we would support parallel importation as a means to supply most societies with drugs. We have a system that now exists, that works, we all know it works. It works best in well-developed

²¹⁵ *Id.*

²¹⁶ *Id.*

countries. It is not working as well in developing countries. There are lots of infrastructure problems that all of us—governments, the private sector—must go into partnership to resolve those problems.

But the patent system as we know it, TRIPS and everything else, is working now. We are being successful, Brazil is being successful, in the existing construct.

What others are proposing: let's get rid of patents, let's undermine TRIPS—we have no experience in the world like that. We have no idea whether it will bring us any success whatsoever. In fact, I dare say if you change the incentive for research, the sixty-four medicines we now have to treat AIDS and opportunistic infections, the 103 medicines that are now in development, you will see less and less of the private sector research dollar going into infectious disease to treat people in poor countries.

To that extent, I believe this movement to demonize the pharmaceutical industry has done an affirmative harm to the very people that they claim to be trying to help.

MR. WARNER: Let me just add a comment. As I look over here, I see Stefanie Niebisch from the U.S. Counsel for International Business in front of me. We were recently at a very interesting meeting at the OECD. Representing the business community, I went back to a meeting in May where this whole issue of international exhaustion was discussed.²¹⁷

As you might know, we have a very different regime internationally than we do within nation states. We have basically the principle of exhaustion at the national level, and the European Union has it at the regional level. There was a division, even among the business community, frankly, when we had that debate, but I tend to come down where Robert does.

In answer to your question, we are in a world where there are these conflicts from time to time, where we do one thing at home and we

²¹⁷ OECD Joint Group on Trade and Competition, "The Economic Effects of International Exhaustion Policies: A Synthesis Note by the Secretariat", COM/DAFFE/CLP/TD(2001)23 (May 2001) (on file with the author).

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have another argument internationally. We are working towards that integrated market, where maybe what we do at home will apply internationally. That might be part of the answer.

I want to thank the panel. We got a lot of the ideas out. It was not quite as much like being in Beirut as I thought it was going to be, and that is good. We are all sticking together, and that is important.

Thank you all for coming, and thank you to the panelists. I think it was a very good debate.