

**INTERNATIONAL ENFORCEMENT OF
INTELLECTUAL PROPERTY RIGHTS
AND AMERICAN COMPETITIVENESS**

HEARING

BEFORE THE

**COMMITTEE ON FINANCE
UNITED STATES SENATE**

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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JULY 15, 2008
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INTERNATIONAL ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND AMERICAN COMPETITIVENESS

TUESDAY, JULY 15, 2008

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Grassley, Kyl, and Roberts.

Also present: Democratic Staff: Bill Dauster, Deputy Staff Director and General Counsel; Amber Cottle, International Trade Counsel; and David Schwartz, Health Counsel. Republican Staff: Stephen Schaefer, Chief International Trade Counsel; and David Ross, International Trade Counsel.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The hearing will come to order.

Thomas Edison said, “Genius is 1 percent inspiration, 99 percent perspiration.” Edison often slept just 4 hours a day. He made his assistants work around the clock. They tested theories, conducted experiments, and filed patents on new inventions. Edison’s genius gave us the light bulb, the phonograph, and the electrical power plant. At the peak of his work, Edison filed a new patent every 11 days. Edison’s genius thrived because of more than just his inspiration and perspiration. His ideas thrived because he worked in an America that fostered innovation and competitiveness.

Edison’s inventions built on the triumphs of the transcontinental railroad and the telegraph. His inventions were fed by unprecedented natural resource discoveries, including the Montana copper that electrified America. He succeeded because he collaborated with other visionaries like Lewis Tiffany and Henry Ford. And Edison succeeded because he locked in each innovation with a patent. By 1910, he had accumulated more than 1,000 patents, almost 1,100.

In today’s America, the genius of modern-day Edisons continues to thrive. It thrives in the workshops of our engineers and scientists, in our advances in software, pharmaceuticals, and the technology industries. It flourishes among our creative artists in music, television, and film.

But today, as in Edison’s time, America’s creative ideas can succeed only in an environment of innovation and competitiveness.

They can succeed only in an environment that protects ideas with values, principles, and laws. They can succeed only in an environment that extends globally, applies rules fairly, and fosters the ideas of the future.

We are here today because our innovative environment is evolving as never before. America's cutting-edge ideas face competition, both fair and unfair, from creative sources around the world. Demand for American ideas is now global in markets new and old. There is no limit to the jobs, the exports, and economic growth that this environment can create.

Yet too often, today's innovative environment appears inadequate. Laws protecting patents and copyrights in the world are uneven, at best. Even in countries with good laws, they all too frequently go unenforced. Pirates and counterfeiters act with impunity. As much as 10 percent of medicines sold around the world are counterfeit. Roughly 90 percent of American copyrighted goods sold in China are pirated. American industries lost more than \$1.4 billion to counterfeiting in Russia last year.

To achieve an innovative and competitive environment, we must identify, deter, and combat the theft of intellectual property in every country. But our laws and agreements must also reflect America's compassion and good sense. We must help ensure that the world's poorest countries have access to lifesaving medicines to treat their sick, agricultural and biological technology to feed the hungry, and green technology to clean their environment.

Finding a new way forward is not merely an academic exercise. American jobs depend on it. Industries that rely on intellectual property protection already account for most American exports. These industries employ 18 million Americans in high-paying jobs, and these workers drive 40 percent of our economic growth.

We owe it to these Americans, and every innovator, to strengthen intellectual property enforcement at home and abroad. We owe it to them to improve the competitiveness of American industries in the jobs that depend on them, and we owe it to ourselves and our values to pursue these goals with compassion and with good sense.

Edison once said, "I have not failed. I have just found 10,000 ways that won't work." Today's hearing is about finding ways that do work. We hope to uncover a little genius, and we hope that we can do so in fewer than 10,000 attempts.

Senator Grassley?

Senator GRASSLEY. Mr. Chairman, I have no opening statement. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Today's panel begins with Andrew Lack, the chairman of SONY BMG Music Entertainment, a global record music company headquartered in New York. Following Mr. Lack is Jeffrey Kindler, chairman and CEO of Pfizer, the world's largest research-based bio-pharmaceutical company. The third witness, John Barton, is professor emeritus at Stanford University Law School. Professor Barton chaired the U.K. Commission on Intellectual Property Rights. And finally, we welcome J. Walter Cahill, the international vice president of the International Alliance of Theatrical Stage Employees, Moving Picture Technicians, Artists, and Allied Crafts.

As is our usual practice, all of your statements will be included in the record. We ask each of you to speak about 5 minutes, and then we will take it from there.

Mr. Lack?

**STATEMENT OF ANDREW LACK, CHAIRMAN,
SONY BMG MUSIC ENTERTAINMENT, NEW YORK, NY**

Mr. LACK. Thank you, sir. Chairman Baucus, Ranking Member Grassley, and members of the committee, Senator Kyl, my name is Andy Lack, and I am chairman of SONY BMG Music Entertainment. Thank you for inviting me today to testify on this issue of intellectual property protection and American competitiveness in global markets.

I commend you for recognizing that this issue is of great importance, not just to the U.S. creative community, but to the U.S. economy and to U.S. society as a whole. This committee has been a tremendous champion for strong and effective copyright protection around the world, and I thank you for your leadership, sir.

I began my career in the world of television journalism, ultimately overseeing all the news programming for a major television network. Eventually, my responsibilities expanded to include entertainment media as well, in motion pictures, TV, and now, of course, music.

But I have always maintained somewhat of a journalist's view of the media world as a whole, and, if I were writing a lead for this story for you today, it would be that America needs to commit more resources to protecting one of its most vibrant and vital sectors and to use our trading power to improve the legal climate for intellectual property abroad.

Now, why? It has been reported that roughly 40 percent of the U.S. economy is dependent upon IP protection in one way or another. A report by the International Intellectual Property Alliance, the IIPA, shows that the core copyright industries are alone responsible for 6 percent of the U.S. GDP, employ more than 5 million workers, and are responsible for an estimated 13 percent of annual U.S. economic growth.

These statistics show how high the stakes are for protecting American intellectual property. The record industry unfortunately tends to be the canary in the coal mine on these issues. This is a crisis that we currently face—the piracy phenomenon—and we face it on two fronts. One involves the traditional physical marketplace in which we confront increasingly organized criminal enterprises which involve massive production and trafficking of pirated CDs. The second front of the piracy war exists in the online marketplace where, with the push of a button, people the world over can obtain perfect digital copies of our creative works for free.

There is now an urgent need to confront this piracy crisis, and any global IP protection regime must address this problem on both the physical and the digital fronts. The U.S. Government has to keep intellectual property protection at the top of its enforcement agenda and ensure that law enforcement agencies have the necessary resources and the underlying legal framework to fight the theft of America's creative products.

Now, with respect to trade, we salute the work that the USTR has done, working with other U.S. Government agencies. They have done this in monitoring the implementation of trade agreements to ensure that our trading partners comply with their IP protection obligations.

We also applaud the U.S. Government for the actions that it has taken to make China accountable for its piracy problem, specifically through the filing of actions with the WTO. We commend the work that this committee has done for the area of trade and IP, and we hope that Congress will continue to play a major role in using trade programs to leverage effective copyright protection abroad.

We are particularly concerned about the rampant piracy problem in Russia and continue to endorse the position taken by the chairman and the ranking member of this committee, that Russia must not be admitted into the WTO until it has complied with its obligations under the IP agreement reached with the United States.

Here at home, we recognize that adequate enforcement requires adequate resources, and I urge the Congress to appropriate sufficient funds in that regard. Law enforcement must have dedicated personnel who are focused on seeking out and stopping illegal trafficking and pirated goods.

We need a better IT enforcement infrastructure, one that elevates the treatment of copyright within the Federal Government so that the best minds and best resources can be devoted to solving this problem. Industry must continue to do its part as well.

In my own organization, we have formed dozens of partnerships with technology and telecommunications companies in an effort to push every opportunity to meet consumer demand. Given the corporate parentage of my company, I always find it odd when people try to frame intellectual property discussions as a debate between technology and content.

In this day and age, the opposite is true. Technology and content are inseparable partners, and they are tied together in this quest to bring entertainment to the consumer in new and exciting ways. With your help, we can get it right. So much is at stake. For our artists and our consumers, for our culture and our economy, this is what we ask you to consider today. Once again, I thank you for inviting me here, and I look forward to your questions. Thank you.

The CHAIRMAN. Thank you, Mr. Lack, very much.

[The prepared statement of Mr. Lack appears in the appendix.]

The CHAIRMAN. Mr. Kindler?

**STATEMENT OF JEFFREY KINDLER, CHAIRMAN AND CHIEF
EXECUTIVE OFFICER, PFIZER, INC., NEW YORK, NY**

Mr. KINDLER. Thank you, Chairman Baucus, Senator Grassley, Senator Kyl, and the entire committee, for inviting me today. I am grateful that this committee understands the urgency of meeting the challenges of global competition and has taken a leadership role in that, and I fully support the opening comments of the chairman.

Pfizer is a research-based bio-pharmaceutical company whose 85,000 employees invent, produce, and provide medicines that save and improve lives. American's bio-pharmaceutical research compa-

nies invest almost \$60 billion each and every year in search of treatments and cures. It is a very risky and expensive enterprise, so our ability to make those investments depends on the protection of intellectual property rights in our discoveries and inventions.

IP equals innovation, innovation equals competitiveness, and competitiveness equals jobs. Of all the industries in the United States, the bio-pharmaceutical industry spends the most on R&D, about \$70,000 for each of our 500,000 employees, including 80,000 of the world's best scientists.

So it is troubling to see intellectual property rights eroding around the world, even, I am sorry to say, in the United States, where it has been a part of our country's economic foundation since before the Constitution was written.

Let me briefly highlight some of these threats, and the chairman has referenced them. Counterfeiting. This crime has exploded with the rise of the Internet. Six out of every 10 pills sold online are fake. Patients think they are importing into the U.S. drugs made by Pfizer or other American companies, but too often those pills were concocted in some dirty basement in a place that lacks our strong safety systems. We saw, last year, adulterated heparin supplies sickening hundreds of Americans. The World Health Organization estimates that thousands of patients around the world have become ill or died as a result of fake medicines.

Counterfeiting is, of course, illegal, but equally troubling are legal assaults on IP. Last year, there were two especially disturbing developments. First, the May 10 agreement on trade in which Congress and the administration revised previously negotiated free trade agreements. Again, I appreciate this committee's leadership on this issue. Even though our trade partners had agreed to strengthen IP rights, the agreement weakened those protections for medical innovations in the areas of data exclusivity, patent linkage, and patent term extension, thereby leaving in place in these countries weak patent protections that allow generic copies to be marketed even during the lives of our patents. This sets a very bad precedent, making it much harder for Americans to compete in these growing countries, which means the loss of American job opportunities.

A second troubling development last year was when the government of Thailand issued compulsory licenses that allowed copying of a wide variety of patent-protected medicines. Now, Pfizer fully supports the flexibilities established by the TRIPS agreement, and I endorse the chairman's comments about bringing common sense and compassion to bear as we address the issues of global access to medicines. But in Thailand, we saw for the first time a country issue multiple compulsory licenses for the purpose of redirecting resources to other budget priorities of the government. Before using compulsory licenses, countries should show an urgent medical need, an IP-related impediment to access, and that good-faith negotiations with the rights holders have failed.

Thailand's approach, if common, would deprive us, and countries like Thailand, of the new and better drugs that they need. Indeed, around the world, innovation should be rewarded, not discouraged, but this important principle seems to be eroding. As we develop

policies going forward, it is instructive to compare the different experiences of Europe and the United States.

In Europe a generation ago, pharmaceutical industries flourished. At that time, 8 out of the world's 10 leading drugs were discovered in Europe. But European governments seeking to respond to budget pressures offered insufficient rewards for innovation, and as a result the industry in these countries withered. In the United States, by contrast, we have preserved incentives for intellectual property, and as a result the industry has prospered, which has benefitted patients, created jobs, improved American competitiveness, and helped the American economy. Today, 8 of the 10 leading drugs were discovered in the United States. We need to bear these different experiences in mind as we develop policy going forward.

Let me conclude by offering a few ideas for your consideration. First, let us strengthen enforcement. Give our government the resources to hold the worst offenders accountable. Second, let us build strong, enforceable IP provisions into our trade agreements. And, finally, we need to expand that exclusivity here in the U.S. We have to stay competitive with countries that now have stronger IP protections than our own. The global threat to intellectual property rights is real. We need to fight that threat and continue to strengthen IP protections here at home. In waging this fight, history is on our side. Protection of intellectual property is in our Constitution. It has served us well for more than 200 years. Let us sustain that legacy as we move into the future.

Thank you.

The CHAIRMAN. Thank you, Mr. Kindler.

[The prepared statement of Mr. Kindler appears in the appendix.]

The CHAIRMAN. Professor Barton?

STATEMENT OF JOHN BARTON, GEORGE E. OSBORNE PROFESSOR OF LAW, EMERITUS, STANFORD LAW SCHOOL, STANFORD, CA

Mr. BARTON. Thank you. I have been asked to testify on the concerns the developing nations have presented in response to the global extension of intellectual property to trade negotiations.

We often do not realize how significant it is to introduce IP policy into world trade negotiations. Traditional trade negotiations were about ways to reduce trade barriers. Because freight trade always economically benefits both the new importers and the new exporters, the negotiators could be confident that they were facilitating the achievement of mutual benefit.

This is not necessarily the case for IP diplomacy. International IP policy is not about free trade, rather, it is about the global allocation of the cost of research. The political nub of dispute in United States patent policy has, of course, been pharmaceutical access and the history of sub-Saharan Africa.

AIDS activists argue there that patents were keeping these nations from obtaining access to anti-retrovirals because the drugs were priced too high. The industry argued in response that the lack of medical infrastructure was the real problem, and that many of the relevant drugs were not patented.

As a formal matter, the dispute was settled by the Doha Declaration of 2001, which stated that public health concerns were to be taken into account in interpreting TRIPS and affirmed the use of a number of TRIPS flexibilities.

Nevertheless, the U.S. Trade Representative has sought to strengthen developing world intellectual property protection and narrow some of those flexibilities, primarily through a series of bilateral trade agreements such as those with Chile and Jordan. Typically, the relevant provisions deal with compulsory licensing, patent term extensions, and data protection.

These agreements have made a difference. Oxfam, for example, has concluded that the consumer costs of certain diabetes and heart disease products were 2 to 6 times more expensive in Jordan than in Egypt, and, although there is no free trade agreement, the World Bank has studied the Thai HIV program and concluded that failing to use compulsory licenses could more than double the cost per life saved of its national program to distribute anti-retrovirals.

The area of current political attention is, of course, the middle-income nations. These nations are the growth pharmaceutical markets of the future. Patent protection is of great importance to the future of the pharmaceutical industry's business model. At the same time, these nations still have many very poor people and, thus, view themselves as reasonably benefitting from the Doha Declaration. I believe that we must attempt new approaches in dealing with these nations. It is in our national interest to facilitate their growth and health. That may call for low—i.e., generic—prices for at least some drugs for some people.

GSK, for example, is developing mechanisms for differential pricing within poorer countries based on charging a generic price to certain public or nonprofit distribution channels, while charging a higher research reimbursement price to others. Might the approach be extended? Compromise seems reasonable.

Imposing such a compromise, it is worth noting that it will necessarily be more complex than a pure IP arrangement. For example, price controls are almost certainly going to be the key topic for future international negotiations, especially with Europe, in the pharmaceutical area. They will probably be an issue in our country as we move towards health care reform. We will need to define effective decision-making standards and procedures that protect public budgets while maintaining optimal incentives for research and medical technology.

All nations want greater access to health care, all want to contain the cost of that health care, all want more advanced technologies. These calls have to be balanced, and the details of that balance may reasonably be different for nations at different income levels. Might we define a global vision that could be the basis of a new central trade agreement governing a number of pharmaceutical issues?

I do not have time to detail either the climate change or the agricultural biotechnology sector but do want to note that I do not favor a Doha Declaration approach for the climate change sector, precisely because royalties are so much smaller a portion of the actual products.

I do, however, believe that it is in the world's interests and in our national interest to transfer technologies to the developing world in all of these sectors, medicine, agriculture, and clean energy. This reflects a humanitarian concern, yet builds markets. It contributes to building a world that is safe for all of us to live in on a long-term basis.

In all three of these sectors, the industries and markets are global, the cost of research is shared by public and private institutions, and expenditure and investment patterns are shaped by a variety of regulatory and pricing regimes, including going way beyond intellectual property.

Each of the areas, I think, is best approached in a sector-specific manner that recognizes the role of IP without overweighting that role, and it seeks to structure the entire world research incentive system in a way that balances the need for innovation with the need for access to that innovation.

The CHAIRMAN. Thank you, Professor, very much.

[The prepared statement of Mr. Barton appears in the appendix.]

The CHAIRMAN. Mr. Cahill?

STATEMENT OF J. WALTER CAHILL, INTERNATIONAL VICE PRESIDENT, INTERNATIONAL ALLIANCE OF THEATRICAL STAGE EMPLOYEES, MOVING PICTURE TECHNICIANS, ARTISTS, AND ALLIED CRAFTS, WASHINGTON, DC; ON BEHALF OF THOMAS C. SHORT, INTERNATIONAL PRESIDENT, INTERNATIONAL ALLIANCE OF THEATRICAL STAGE EMPLOYEES, MOVING PICTURE TECHNICIANS, ARTISTS, AND ALLIED CRAFTS, WASHINGTON, DC

Mr. CAHILL. Good morning. My name is Walter Cahill. I am a vice president of the International Alliance of Theatrical Stage Employees, here on behalf of Thomas C. Short, IATSE international president, who is unable to be here due to scheduling conflicts.

I would like to thank you for the opportunity to address the committee on the issue of intellectual property protection. I commend Chairman Baucus, Ranking Member Grassley, and the other members of the committee for holding this hearing.

The IATSE was founded in 1893 by a group of stagehands in New York City and has expanded throughout our 115-year history with local unions chartered throughout the United States and Canada. Today, the IATSE is the largest entertainment union in the world, with nearly 120,000 members who are employed in legitimate theater, motion picture exhibition, convention and trade shows, motion picture and television production, radio and television broadcasting, and various other crafts of the entertainment industry.

The mission of the IATSE is to provide the finest reputation for our members and protect their best interests. In doing so, it is incumbent on the leadership of our union to negotiate with employers in a fair and equitable manner, thereby obtaining the best possible wages and benefits for our members. The benefits we negotiate are critical to the times in which we now find ourselves, including the extreme challenges we face with the health care crisis in this country.

As it applies to benefits for our members, the issue of combatting the theft of intellectual property is of paramount concern to us. Our members are employed in the entertainment industry and are hardworking people who do not earn millions of dollars to make one movie, such as some of the high-profile actors with whom most may be familiar.

The number of individuals employed on the production of any given movie may be anywhere from 200 to 1,000. These members have to make their paychecks last much longer than other workers because these are not permanent jobs. They are jobs that will end when production is complete, and the next job they get may not be for months.

Because of the nature of our business, we have attempted to ensure that our members and their families are taken care of by securing additional revenue to be provided for them in the form of residual payments. In the IATSE, these payments are contributed into the health and retirement benefits that our members so desperately need. When studios release DVDs to the market, our members share in the profits of those sales through these residuals.

In our industry, intellectual property theft, or piracy, occurs with the illegal copying, reproduction, and distribution of motion pictures. When these pirated copies are sold on the street or downloaded from the Internet, our members, and many other workers, see nothing. In fact, every year the members of our union experience a loss of roughly \$100 million to the health and pension funds due to intellectual property theft.

Piracy is stealing, pure and simple. Downloading a movie without paying for it is the same as stealing a DVD off the shelf of a store. The victimless crime mentality portrayed in old-fashioned Hollywood movies is, unfortunately, how much of the public still perceives this theft. Piracy is not a petty, victimless crime. It is not perpetuated solely by kids with camcorders and bargain hunters prowling the Internet. It is a devastating economic attack that, in 2007 alone, cost our industry \$6 billion. As large as that sum is, it is only a fraction of the \$250 billion that copyright piracy and counterfeiting costs the overall U.S. economy every year.

A recent study revealed, in 2005, that piracy deprived State and local governments of \$837 million in tax revenue. As residents of those communities, that is money out of our pockets, money that could have gone toward schools, roads, and other infrastructure in our communities.

To eradicate this plague, first we need to educate ourselves, our families, and our friends. We need to stop the theft we know about. We need to recognize piracy and who it actually hurts, and inform those around us about the facts. Just as this society punishes bank robbers, this society should, with just as much force, punish those pirates who rob our industry of its product.

Second, from our elected leaders we seek support and sponsorship of stronger legislation protecting intellectual property. We have an obligation to work with you to strengthen existing laws and enact new laws that protect us. After all, the movie industry is a significant portion of our economy. Each year it accounts for about 1.3 million jobs, pays \$30.24 billion in wages, and \$10 billion

in Federal and State taxes. We all benefit from a thriving movie industry. The loss through piracy of \$6 billion in 1 year is unacceptable.

The entertainment industry is no corner candy store, and motion picture pirates are not a scruffy gang of teenagers looking for kicks. Piracy has become a highly-evolved criminal enterprise that is robbing billions from our industry. It is the theft of someone else's property and robs from those whom we believe work the hardest in the industry: IATSE craftspeople.

Protecting the motion picture industry benefits everyone. The IATSE has been working with members of a broad-based coalition, the Coalition Against Counterfeiting and Piracy. I would urge the committee to give positive consideration to the proposals this labor/business coalition has put forward with respect to Customs and Border Protection. I also think it worth noting that the AFL-CIO, as well as many of its affiliates, are supportive of legislation that will help eradicate this problem.

On behalf of the IATSC, I am particularly appreciative of this opportunity to present testimony to you. I thank this committee for inviting us to participate in your hearing and in allowing us to provide information we feel is important for you to know and consider when legislation is to be formulated, proposed, and acted upon.

Thank you.

The CHAIRMAN. Thank you, Mr. Cahill, very much.

[The prepared statement of Mr. Cahill appears in the appendix.]

The CHAIRMAN. I would like to focus a bit on the tension between protecting intellectual property on the one hand and the need to help some of the developing countries on the other. We have the Doha Declaration, the May 10th agreement. I would like, frankly, Professor Barton and Mr. Kindler, if you could kind of help us find a compromise here, help us find a way to get to the bottom line here, what this is really all about, and how can we resolve this in a way that is fair to both sides, because I think there are two great, important values here to protect and to address. If you could just help us a bit, that would be helpful.

Mr. KINDLER. Well, maybe I could start, with Professor Barton's indulgence, by identifying common ground, which is, I certainly agree with Professor Barton, that we need holistic solutions. Professor Barton said those solutions should not overweight intellectual property as an issue, and I would like to suggest they should not under-weight it, either. My concern has been that IP has been seen as the single way to address these issues, and clearly the issues are much broader than that. The head of the UN AIDS Department has said that if the cure for AIDS were a single glass of clean water a day, we would not be able to provide that to half the AIDS patients in the world.

So, clearly, infrastructure problems, access, health care systems all have to be looked at holistically. I would agree with Professor Barton that we should take a comprehensive view of this issue. I would hope that in that context we could have IP protections and recognize we could be much clearer about the circumstances, for example, in which a compulsory be licensed.

So, for example, in the case of Thailand, the compulsory licenses may extend to a wide variety of medicines, many of which do not

require that solution to address health needs and that are being used fundamentally for budget reasons where the government is purchasing lower-cost products and actually marking them up themselves and making a profit to sell them. So that is taking the flexibilities of TRIPS, in my view, too far.

Having said that, the flexibilities of TRIPS are very important. So I would encourage, and I think the WHO Intergovernmental Working Group did a very good job of looking at this as a comprehensive issue that recognizes the importance of intellectual property, recognizes the need to address access issues which cannot be done either by industry alone, by governments alone, or by non-governmental organizations alone. We need to all work together on that. The pharmaceutical industry—and I will not belabor it this morning—has, we think, a very proud record of doing what we can to enhance access. But clearly, much more needs to be done.

The CHAIRMAN. All right. I am going to have to give Professor Barton equal time here.

Mr. KINDLER. That is fine. Thank you.

The CHAIRMAN. All right. Thank you very much, Mr. Kindler.

Mr. BARTON. Let me start also by noting some points that I think are in common. I think we are both agreed that sub-Saharan Africa should get generic prices.

The CHAIRMAN. Mr. Kindler, did you hear that?

Mr. KINDLER. Yes. For life-saving drugs that they need, absolutely. They represent a very small portion of pharmaceutical sales.

The CHAIRMAN. Thank you.

Mr. BARTON. Agreed. Agreed. The big problems at that point are now the access kinds of issues that Mr. Kindler mentioned. Indeed, we have now reached something like 30 percent of the world's HIV people who need anti-retrovirals in low- and middle-income countries. The reason that it is not 100 percent is not the drug industry; the reason is almost certainly the infrastructure and the problems of counterfeit drugs, et cetera, et cetera, et cetera, a variety of problems I suspect we would be in agreement on.

Having said that, I think I begin to see a solution when I say, again, I am not so sure that the patents are as essential as they seem to appear in Geneva, all the discussions there. I think the real issue is, in many respects, the buying policies of the global fund for AIDS, TB, and malaria, the buying policies of PEPFAR, the President's Emergency Plan for AIDS Relief. These are the people who are going to supply the drugs to the poorest.

Now I get to the tricky questions: the middle-income countries, Thailand, India. There are more poor people in India than there are in sub-Saharan Africa. What do we do about that? That is why I think we need some compromises in nations of that type.

I wonder if the compromises are best structured in the way of some form of global arrangement that begins to deal with counterfeits, begins to deal with the risks of price controls which are going to, in my judgment, affect the future profitability of the industry, probably significantly more than intellectual property. So I am wondering if there is some kind of sectoral deal that goes beyond the traditional intellectual property bilateral trade agreements.

The CHAIRMAN. Do you have any response to that, Mr. Kindler? Your thoughts about that.

Mr. KINDLER. Well, I am not exactly sure what Professor Barton might have in mind. I will say, we clearly price differently in different countries, and even within a country there should be differential pricing because, while there are vast numbers of very impoverished people in India, without a doubt there are also some people that can afford medicines. India is a country itself, and Brazil is another example of this, where intellectual property protections are good for their growing economy. So I think it is not a one-size-fits-all solution globally.

The CHAIRMAN. My time has expired. But I am just reminded that a lot of the solutions in several countries of the world are just a better health infrastructure and water system, and clean water and so forth. I read, about a year and a half ago, an article in *Financial Times*. The dollars that the Western World—Europe, the United States—spends on bottled water in a year are enough to establish drinking water systems throughout Africa. So to some degree, it is important to think about our values in that sense, too.

Senator Grassley?

Senator GRASSLEY. Thank you, Mr. Chairman.

Mr. Lack, the indication we have received from Chinese officials is that China is making significant progress in cracking down on the theft of foreign intellectual property. I want your reaction. More specifically, have you seen any improvement in China's protection of your company's intellectual property? How satisfied are you?

Mr. LACK. Well, no question, the Chinese see this on the agenda more seriously than they did several years ago. But candidly, we do not see enough progress. That is where, as I mentioned in my remarks, we need leadership, the kind of which we are getting here in this committee, and we need enforcement. They need to understand there are consequences for the piracy problems that we are seeing in that country.

So while I think the conversations have become a little bit more constructive, the dialogue is there, I do not think they still see the seriousness of purpose and the effect that it has on our economy. I do not think they fully understand or appreciate the consequences to our economy, and to our industry in particular, the entertainment industry. But they are beginning to show signs that they appreciate and are trying to understand a little bit better.

Senator GRASSLEY. Have the people in our bureaucracy who have the responsibility for the enforcement of this been forceful enough, from your point of view?

Mr. LACK. I do not think so, sir. No.

Senator GRASSLEY. Is it pinpointed enough, the people who have the responsibility to do this, or is there too much division within our executive branch?

Mr. LACK. Yes, I think within our executive branch there are a lot of good efforts, but it is not clear every day who gets up and is empowered with driving the results that we need in order for there to be true and meaningful progress.

Senator GRASSLEY. Would we be better off if there were such a pinpointing?

Mr. LACK. I believe so, without question. I think—for example, Mr. Kindler would agree with me—as businessmen, we know that

you do not get results unless you drive them every day, unless there are individuals who are empowered to get those results. On every team, if you do not have that kind of leadership pushed down through the organization at every level, interfacing with the Chinese at the same levels, you do not get the results.

So even though Secretary Paulson, Secretary Gutierrez have been excellent in commenting on these issues that are of such concern to us at their level, we do not see underneath them the kind of drive to get the real actions that make the meaningful differences that you are speaking about.

Senator GRASSLEY. Without my repeating the question—it is similar—for Russia, state the situation your company has with Russia and explain if they are making any progress, and how it affects your business.

Mr. LACK. Yes. Well, to a lesser degree. Russia, as you know, is not part of the WTO.

Senator GRASSLEY. Yes. And we have argued the same way you have, that they should not be until they make this commitment.

Mr. LACK. I think that is exactly right. I think that is the only way that they appreciate and respect the seriousness of this issue for us. Piracy, quite candidly, in Russia is rampant. To reference my colleague at the IATSE, Mr. Cahill, piracy is too romantic a word: it is stealing. Unless you put it in that context to them, unless they understand what the consequences are of that to us, they do not recognize it as a problem in the context that we are trying to discuss it today.

Piracy romanticizes, almost, the notion of what in fact we are dealing with. They are seriously damaging us, through the infrastructure that they have, not being able to enforce the agreements that we have with them. They are seriously damaging us. So we have some constructive dialogue there. We are actively working to get those relationships in a better place than they are today. We want to do business in Russia. We want to get value out of our good work in Russia. But candidly, I would have to say at this point, we are a long way from getting the kind of progress we need to satisfy our issues.

Senator GRASSLEY. Mr. Kindler, you testified that we should add more teeth to the Special 301 process. Some specific changes you would like to see? And before you answer that, I would like to make a comment and thank you about your efforts to develop miracle drugs. But I think left out of the debate that you had with the chairman here, and also Mr. Barton, is an appreciation around the world that, if you are going to have miracle drugs, they are going to be paid for by this generation for the next generation of miracle drugs. There is no free lunch here. That is a point.

Would you answer my question about 301? Then I will stop.

Mr. KINDLER. Yes, sir. I am not a trade expert and would not want to offer overly specific suggestions, but I would say that 301 now does a very good job of identifying countries that have issues. We would like to follow up on that with regard to more governmental and intergovernmental pressure on those countries that are not acting in accordance with trade relations and trade provisions.

I also believe, and it is not inconsistent, Senator, with the dialogue you just had with Mr. Lack, that I think even greater focus

and resources within USTR, addressed to this very specific issue, would be very helpful. There are a lot of terrific people in USTR working on this issue, but frankly the problem is quite overwhelming. Again, identifying, as Mr. Lack said, some clear accountability, empowerment, and resources to address the issue would be very helpful there as well.

Senator GRASSLEY. Thank you.

Mr. LACK. If I could just add one other comment that references something that the chairman said earlier that relates to Russia as well, Senator Grassley. Just to give you an example, in Russia, which Senator Baucus mentioned earlier, what kind of environment are we creating for intellectual property protection, when the head of the Collection Society in Russia was assassinated? The reality is, on the ground, it is a very tough atmosphere to get the respect and the understanding of what we need to get done in order to protect intellectual property here.

The CHAIRMAN. Thank you, Senator Grassley, very much.

Senator Kyl?

Senator KYL. Thank you, Mr. Chairman.

Let me just first note, Mr. Chairman, since there was some discussion about how we could just spend a little bit more on water and help folks, we will have an opportunity to do that with regard to the bill that is pending in the Senate right now, the so-called PEPFAR bill, which provides aid primarily to Africa to deal with malaria, AIDS, and tuberculosis.

What I have done—and I want the chairman to hear this—is that I have offered an amendment to take just \$1 billion of the \$50 billion that would otherwise go to develop water projects, as well as deal with AIDS and other developmental issues, in Africa and apply that to America's Indian reservations.

According to the Indian Health Service, 11 percent of American Indians and Alaskan Native homes do not have adequate drinking water. In fact, on the Navajo Nation, 30 percent of the households on the reservation do not have access to a water system. They have to haul their water. It clearly results in greater incidences of disease and the like.

So, we will have an opportunity to focus even on our country with the trust responsibility we have to our own Native American citizens to deal with that problem here in the U.S.

Let me just say that I very much agree with the comments of those of you on the panel who have urged greater efforts at enforcing our laws, more resources to be devoted to the problem, and a greater use of our trading power. I think those are important points.

In that regard, I was very disappointed when the May 10th agreement was negotiated, for the reasons that were pointed out here. After the countries that we were negotiating with had already agreed to the provisions that we asked for, we went back and weakened those provisions. That sets not only a very bad precedent, but I think might have other deleterious ramifications. I wanted to ask Mr. Kindler a couple of questions in that regard.

How do you see the impact of that May 10th agreement on R&D expenditures and jobs here in the United States? Does it have an impact?

Mr. KINDLER. Certainly, Senator Kyl. Let me just add one thing to what you said, first, which is that the irony of this is that, if you take Colombia, for example, they had actually adopted a law providing for data exclusivity, and the trade agreement simply reinforced that they were going to do so. They agreed to that. Then we took that provision out and they went back to their legislature and said, well, maybe we do not need that.

I agree with you, Senator, this is a terrible precedent because the message we are sending to these nations is—even those that are willing and interested for the benefit of their own economy and improved trade relations to improve their intellectual property environment—we are telling them they do not have to do that. I, quite frankly, do not understand why we would take that position.

Now, in the long run, I gave the example of Europe. There is no question that our industry—and I am sure Mr. Lack would say the same, and the same point was made with regard to the unions—is completely dependent on intellectual property, and there is a direct relationship between jobs and our ability to invest in research on the one hand, and intellectual property. I will just give you one small example. This is in the U.S., but it is certainly true all over.

We had a patent lawsuit that we lost in the District Court, which we expect to win in the Court of Appeals, but, in the interim, generics came in and we had to close a plant and shut down 600 jobs. There is a direct relationship between those. There is a relationship between our ability to provide drugs to the developing world, to invest in research, and ultimately in jobs. There is no doubt about that.

Senator KYL. Of course, far more important than jobs to me is the innovation that results in the great products that make life better and longer for all of us everywhere in the world.

The other concern I had was the impact on both the current FTA partners that we have and future FTA partners on their willingness to include stronger IP protection, given what we have negotiated, again, in the context of the May 10th agreement.

Mr. KINDLER. Yes. Again, I think that you are absolutely right, Senator. Why would the next partner agree to provisions of this nature, or even independent of the trade agreements, adopt intellectual property protections when we have basically signaled that they do not have to? I also find it very disturbing that the pharmaceutical industry in particular was singled out for these dilutions in intellectual property rights in this context.

Senator KYL. Well, thank you. I thank all of the witnesses here on the panel, and Mr. Chairman, for holding the hearing. It is clear, as you pointed out in your opening statement, that protection of property rights is one of the foundations of our economy, of any market economy, and the beauty of it is, it is the opportunity to create better things for everyone which then results from that protection. We need to do everything to not only legislate those protections, but ensure that they are enforced in the ways that at least three of you on the panel have indicated we need to do. So, I appreciate that very much and appreciate your testimony.

Mr. KINDLER. Thank you, Senator.

The CHAIRMAN. Thank you, Senator.

Senator Roberts, if you are ready, you are next.

**OPENING STATEMENT OF HON. PAT ROBERTS,
A U.S. SENATOR FROM KANSAS**

Senator ROBERTS. Well, thank you very much for having this hearing. I apologize I am late, but we are having a hearing on the ADA and the responsibilities we have to the disabled just one floor down. Thank you very much for your leadership in having this. I have already started to study, through staff and myself, the statements of the witnesses. Thank you all for coming, taking the time out of your schedule to do that.

We have seen a lot of technology increase—I do not know if anybody has brought this up or not—not only on the level of production, but expanding a variety of crops that can be produced over a wide range of cropland. There is a lot of news about the food price situation today. We have a lot of research and development that have expanded the options available for agriculture producers worldwide.

Not too many people know that when Stephen Foster wrote the song, “Those Old Cotton Fields Back Home,” that he was referring to Kansas. It is not uncommon now to see cotton fields in the southwest part of Kansas, a crop that was previously only found in the southern States. So with the new variety that allows for shorter growing seasons, why, Kansas is a cotton producer. Then we also boast high-technology companies, one in particular that produces a product that impacts us in our daily lives.

I am talking about Garmin International, something you may have on your car in regards to navigational software and for mobile phones. Who, at some time, has not wished, with your wife telling you that you should stop and ask for directions, and you keep on driving, that you could have something that could tell you exactly where you are and where you should go? Garmin has been producing the solution for some time.

Now, they are keenly aware of how strong protection of intellectual property helps them to ensure their competitiveness in the world market, and they have faced challenges with copyright infringement of their technology and the enforcement of the copyright law. It is not relegated to developing countries only, but is a problem, in particular, with members of the EU. So, digital copyright infringement is a serious challenge, and Garmin tries to combat this in the Internet age, where the navigational maps they provide are available illegally to download from servers outside the U.S.

So, thank you for the hearing, Mr. Chairman. We must work to craft the correct policies that both protect and continue to foster American innovators and competitiveness while balancing the moral and ethical obligations that come with ingenuity. So basically, I hope that we can work with the WTO on these issues, although the WTO right now is sort of moribund in regards to the trade situation that we have here in the Congress.

I thank everybody for being here, and thank the chairman for holding the hearing.

The CHAIRMAN. Thank you, Senator, very much.

I would like to go back to Mr. Cahill a little bit here. I think it is an important point that not many people really understand or realize, namely that, not only do companies lose when CDs are pi-

rated, but you lose because your compensation is dependent upon sales of CDs. Is that correct?

Mr. CAHILL. Yes, sir, it is. As I said, our union loses \$100 million annually into our pension and health funds, and it hurts our employers. Our employers are losing the market share that they would get if they were receiving the royalties that they are supposed to get. It is no different than stealing a DVD off the shelf of a store.

The CHAIRMAN. So it is theft of a product from the company, it is a theft from you, a theft from your membership.

Mr. CAHILL. We all lose, sir.

The CHAIRMAN. They are stealing from you.

Mr. CAHILL. They are stealing from us. Yes, sir.

The CHAIRMAN. Again, I do not think that is well understood, and I appreciate your making that point.

I do not want to drive this point too far, but I am trying to find a way to get you, Mr. Kindler and Professor Barton, a little closer together still.

Mr. KINDLER. We agreed a moment ago.

The CHAIRMAN. You had a little private side agreement here?

Mr. KINDLER. We are going to go off together and see if we can solve this for everyone. We actually, I think, have a fair amount of comity.

The CHAIRMAN. I was going to suggest something like that.

Mr. KINDLER. Yes.

The CHAIRMAN. Is there a way for the two of you and your people to sit down and work more closely toward common ground and help us out a little bit?

Mr. BARTON. I would look forward to that, and appreciate your leadership in bringing us together. I would be honored.

The CHAIRMAN. That would be great. We will figure out some way.

Mr. KINDLER. We will have it all worked out by next week. [Laughter.]

The CHAIRMAN. For a while, I was encouraged. [Laughter.]

Mr. KINDLER. No. I think, in all seriousness, Chairman Baucus, there is common ground here. I was grateful to see in Professor Barton's testimony that he does, of course, recognize the importance of intellectual property, and his point is, that is not the only issue here, there are many others. We completely concur with that.

The CHAIRMAN. All right. What about, say, a month from now? How does that sound?

Mr. KINDLER. We can try to come up with something, certainly.

The CHAIRMAN. I deeply appreciate that.

Mr. KINDLER. We will make every effort.

The CHAIRMAN. I know I can speak for the committee and say how much we deeply appreciate it.

Mr. KINDLER. We will make every effort.

The CHAIRMAN. Because you know so much about this issue. You are on the ground, you know it. It would help us if you could do so.

Mr. Kindler, your thoughts on Special 301. Currently the administration has put China and Russia on the 301 watch list. The

question is, how do you force, encourage, cajole, prod, require an administration to put other blatant abusers on the watch list?

Mr. KINDLER. Well, I think, as I was saying earlier to Senator Grassley, and very much consistent with Mr. Lack's comments, that the USTR, I think, does a really excellent job of identifying the issues, and they have a superb staff. But they could use more resources, clearer empowerment, clearer accountability and have an even stronger opportunity to really focus on these issues. I believe they would welcome that if Congress would provide them with those resources and that focus.

The CHAIRMAN. It would be helpful if you, Mr. Lack, could pinpoint a little more specifically where those resources should be dedicated and what functions should be enhanced with more resources. If you could just give a little more focus here, because resources in the abstract is one thing, but resources a little bit in the concrete is something else.

Mr. KINDLER. Can I provide the committee with that after having given it a little bit more thought?

The CHAIRMAN. Absolutely. You bet.

Maybe off the top of your head, Mr. Lack, do you have some thoughts, too?

Mr. LACK. Well, people is really where it starts. We need more people engaged in this process in various departments and agencies. I will give you just one example offline. The State Department has a fund to deal with helping foreign governments protect intellectual property. That fund has \$3 million in it. That is not going to go very far around the world toward solving the problems that we are talking about here this morning, so they need a lot more people to administer a larger fund.

Those funds need to be placed in different agencies, whether it is USTR, State Department, or all the various organizations and agencies in the government that have an opportunity to apply some pressure in these issues. If you have people in all of those departments, as I was saying earlier—and I think Mr. Kindler would agree—if you have a team of people who are talking to people across agencies but have a common issue of tackling international piracy and international theft as it affects international copy protection and copyright, that team knows who they are, talks to each other every day, and goes and tackles these issues country to country.

But they need more people to be able to do that. They need to have teams underneath them. So, as we look at it as a business, as business organizations, what is the structure in each of our departments to get the results that we require to have some impact on this issue? That is where I would start.

The CHAIRMAN. What about other countries' efforts? We are not the only country in the world. Sometimes we like to think we are, regrettably, but we are not. I remember reading somewhere that, when was it, there were more patents from Japan, Japanese scientists and engineers, at one point than in the United States. I may be dead wrong on that, but the point is, there are lots of other countries in this world.

So that raises a couple of questions. One, how aggressively are those countries seeking IP protection for their people compared to the U.S.?

Mr. LACK. Well, just quickly, it is fair to say, not nearly as aggressively as we need. There again, it is people having relationships, constructive relationships with their counterparts in those countries on the ground that can drive the results. Right now, we just don't have that kind of depth, I think, to get at these kinds—the endemic nature of this problem.

The CHAIRMAN. Mr. Kindler?

Mr. KINDLER. I would only add that I agree with Mr. Lack, in general. I think that in western Europe there is increasing concern and awareness of this issue. The United Kingdom had a number of issues regarding counterfeit drugs entering its borders, and that has created greater attention and focus on it. The EU trade commissioner is focused on the issue. But I do not think I can identify anybody that I would say is pursuing this to the extent and with the resources that it requires.

The CHAIRMAN. Professor Barton, you are kind of an expert in the U.K.

Mr. BARTON. I think the U.K. is certainly doing much the same things as the United States, probably a little bit more balanced. But sort of bearing down on the copyright issue or different patent issue, the European Parliament just passed a decision in November that called for a Doha Declaration type of arrangement for climate change technologies.

As I mention in my testimony, I do not think that is needed. I think the entire dynamics of the industry structure is completely different in those technologies, but nevertheless this suggests that there is certainly the same kind of concern with enforcing intellectual property, but I think it is significantly weaker than it is in the United States.

The CHAIRMAN. And what do we do to help strengthen their efforts, the European efforts? We have to do this together, it seems to me.

Mr. BARTON. Well, I think there is a good relationship between USTR and the EU trade ministries. I think there are efforts for cooperation in that regard, and the anti-counterfeiting efforts, to some extent, are having a global reach through Interpol and the like.

The CHAIRMAN. Some suggest a new TRIPS-plus, ACTA, the Anti-Counterfeiting Trade Agreement, where countries get together with common interests outside of WTO. The thought is, because WTO is consensual, you would probably get an agreement. Maybe the U.S., European, other countries bind together. The thought is, too, that, once there is momentum there, that that would pull other countries in, too. Is that an approach that makes sense?

Mr. BARTON. I think the question is, what is included in the TRIPS-plus? I think many of us would feel that many sectors of intellectual property, not so much the ones we have been talking about today, can get too strong and can hurt innovation if you go too far. I think there are some concerns that this has happened in some areas of biotechnology.

I think there are concerns that it has happened, say, in copyright and some patent protection of business software and business methods, and so forth. I think we need, very quickly, if we are going to go down a route of that type, to ask, which are the ways we want to strengthen intellectual property, and are we choosing wise ways to strengthen it or are we sometimes choosing unwise ways?

Mr. KINDLER. I would just add that I agree with your comment, Chairman Baucus, that the WTO is a very difficult organization to get clarity on. That is because of the very different interests involved, although I do think their Intergovernmental Working Group made some significant progress. But having said that, if your suggestion is that there are countries that have common interests in this area that could work together and try to adopt solutions that make sense for them because of their different positions, I think that does make a lot of sense, because, the way the WTO is structured right now, it is very difficult to get to a resolution in that sense.

The CHAIRMAN. Professor Barton, you are not wild about the act the British Parliament took.

Mr. BARTON. About the which?

The CHAIRMAN. British Parliament. To include, what, climate change?

Mr. BARTON. Right. European Parliament.

The CHAIRMAN. The European Parliament. That is right. How do we address the global management of climate change? What forum, if any?

Mr. BARTON. I think it is going to be very difficult. I think there are going to be significant technology transfer components and, therefore, inevitably some intellectual property questions. Clearly, the balance has to be in some way. We provide some technology to countries like India and China in return for their committing to ceilings, formally or informally depending on what approach ends up getting taken.

I think that is going to be very easy in some contexts, like, let us say, windmill technology, where there are U.S. industry leaders, there are European industry leaders, there are some Indian companies. I do not know that we have to pay some royalties, but the royalties are not going to be more than a percent or two of the overall price.

The problem is going to be finding the investment capital. I think it is going to be a very difficult question when we deal with things like clean steel-making technology, because we are going to see competition between the resulting Chinese industry and the resulting U.S. and European industries. I think when we come to questions of that type it is going to be a very difficult problem as to how we can find a deal that will work and will actually achieve some climate technology distributions, some control on carbon dioxide emissions.

The CHAIRMAN. Do you have the beginnings of an idea on how to approach that?

Mr. BARTON. I do. I do not yet for steel, but I have some ideas on how to approach it for the electricity production: biofuel, automobiles, housing. But in cases where we are dealing with traded

commodities like steel, there is going to be a big tension between the developed and the developing countries. I do not know how we are going to handle that one yet.

The CHAIRMAN. Autos are somewhat traded. How do we deal with autos?

Mr. BARTON. Yes. But on the other hand, the auto issue is a relatively straightforward one in which the issue is, in essence, encouraging China to make hybrids, providing the technology for hybrids, providing the technology for use of flexible fuels, ethanol versus gasoline, and so forth. Those technologies are quite readily shared within the industry today. My guess is, they will be shared in the future.

I suspect that we will all be relatively comfortable letting the Chinese consumer pay the increased cost of a Chinese vehicle that includes emissions controls, higher fuel efficiency, whatever we are seeking to achieve. That is going to be a quite different world, retrofitting the thousands—or at least hundreds—of coal-based electricity production systems that China is installing. That is going to be hard, and a very expensive problem for someone.

The CHAIRMAN. Clearly, these problems are more complex as the world becomes more globalized—IP, climate, and so forth.

This has been very helpful. Thank you very much. I look forward to, 1 month from now, getting the final deal.

Mr. KINDLER. Yes, sir. Thank you for your leadership.

The CHAIRMAN. Thank you very much.

The hearing is adjourned.

[Whereupon, at 11:11 a.m., the hearing was concluded.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

STATEMENT TO THE
SENATE FINANCE COMMITTEE
HEARING ON
INTERNATIONAL ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS
AND AMERICAN COMPETITIVENESS

JULY 15, 2008

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I have been asked to testify on the concerns that developing nations have presented in response to the global extension of intellectual property (IP) through trade negotiations.

I am the George E. Osborne Professor of Law, Emeritus at Stanford, where I've taught and written on both technology law and international trade issues over the years, with a special focus on developing nation concerns. I was chair of the 2001-2002 U.K. Commission on Intellectual Property Rights. Our report, *Integrating Intellectual Property Rights and Development Policy*, reflected many discussions with developed and developing nation officials and scholars, pharmaceutical firms, and patient advocacy groups. I have also consulted for many years with the international agricultural development community, and have recently written on IP and transfer of climate change technologies.

My presentation has four components. I will first consider the role of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) TRIPS and IP trade policy generally as it affects developing nations. I will then explore, in turn, pharmaceutical, agricultural, and climate change issues.

TRIPS and IP trade policy. It is not often realized how significant it was to introduce IP policy into world trade negotiations. This introduction has been sought by the U.S. government since the 1980s, both through negotiating TRIPS in the Uruguay Round and through bilateral diplomacy. Traditional trade negotiations were about ways to reduce trade barriers. Because free trade almost always economically benefits both the new importers and the new exporters, the negotiators could be confident that they were facilitating the achievement of mutual benefit. Admittedly, they were working within a politic context that focused on specific new exports and specific import concerns of specific industries, but ultimately they were benefiting all.

This is not necessarily the case for IP diplomacy. To take the pharmaceutical patent example, strengthening IP in a nation that imports pharmaceuticals from the United States normally implies that the citizens of that nation pay more for pharmaceuticals. This is hardly a benefit, and it is disingenuous to describe weak IP as a trade barrier – when a trade barrier is removed, the domestic price generally falls rather than rises. The counter argument is, of course, that the participation of those citizens in the global market at a patent-based price creates an incentive for research. In that sense, they may ultimately benefit. But, on their own, they might have chosen a different balance between short-term current costs and long-term research benefits. International IP policy is thus not about free trade. Rather, it is about global allocation of the cost of research. It is certainly reasonable that other wealthy nations should not be entitled to

free ride on the benefits of U.S. research, but it is also reasonable that the poor should not have to pay as large a share of those research costs as the wealthy.¹

Indeed, for small poor nations, the benefits of a patent system are minor if not negative: there are few or no local scientists and engineers who can benefit from the possibility of obtaining a patent, the local market is too small to provide any serious return on investment, and the building of a local patent bureaucracy is an absurd waste of resources. Not surprisingly, the majority of the patent holders in such nations are foreign firms. The World Intellectual Property Organization, for example, estimates that Peru granted 383 patents to non-residents and 5 to residents in 2005.² (It is hard to find reliable data for smaller or poorer nations.) The TRIPS agreement makes no provision for exclusions for small poor nations. It serves neither these nations' nor the U.S.'s interests to pressure these nations to build a patent system.

Pharmaceutical issues. The political nub of dispute over the U.S. patent policy has, of course, been pharmaceutical access. One of the key diplomatic goals of TRIPS was to change the policies of nations such as India, which had denied product patent protection to pharmaceuticals, and thus produced copied generic versions of the developed world's patented pharmaceuticals. The drug access issue came to wide political visibility in 1998 with the filing of a suit by a number of pharmaceutical firms to try to keep South Africa from importing certain generic antiretroviral drugs that would infringe patents in that nation. That litigation was settled in 2001 – but was a major public relations disaster for the industry. It exemplified a multi-year debate over the terms of access to antiretrovirals to deal with the AIDS epidemic sweeping Sub-Saharan Africa. AIDS activists argued that patents were keeping these nations from obtaining access to such drugs, because they were priced too high. The industry argued in response that the lack of medical infrastructure was the problem, and that many of the relevant drugs were not patented.

As a formal legal matter, the dispute was settled by the Doha Declaration on the TRIPS agreement and public health, an agreement reached at the World Trade Organization Ministerial meeting of 2001. This Declaration stated that public health concerns were to be taken into account in interpreting TRIPS and affirmed the use of a number of TRIPS “flexibilities,” including compulsory licenses. Detailed arrangements were negotiated over the next several years to allow the international sale of generics to nations that could not create their own industries. The Doha Declaration result was very understandable considering that the total pharmaceutical market in the poorest nations was at most on the order of 2% of the global market. Any injury to the economic interests of the industry or to research incentives for the future was minor compared with the benefit to the world (and to U.S. interests) of making the drugs more readily available.

¹ See, J. Barton, “The Economics of TRIPS: International Trade in Information-Intensive Products,” 33 *George Washington Int'l Law. Rev.* 473 (2001).

² World Intellectual Property Organization, *WIPO Patent Report*, 2007.

Nevertheless, there is now contention arising from the fact that the USTR has sought to strengthen developing world IP protection – and narrow some of those flexibilities – primarily through a series of bilateral trade agreements, such as those with Chile and Jordan. Typically, the relevant provisions deal with compulsory licensing (a mechanism of overriding a patent, that often leads instead to negotiated reduction in the royalty), patent term extensions, and data protection (limitation on the circumstances under generic drugs can be granted marketing approval on the basis of information in another firm’s regulatory submission). In its 2008 Priority Watch List, for example, the United States specifically criticized Argentina, Chile, India, Pakistan, and Venezuela on this last issue. Many developing nation officials and medical activists criticize these efforts, and view the United States as violating the Doha declaration by seeking to take away the flexibilities of TRIPS.

The critics have a point and the bilateral agreements have actually impacted public health. Oxfam, for example, has studied the impact of the U.S.-Jordan Free Trade Agreement of 2001, and concluded that since it was negotiated, medicine prices have increased by 20%, the consumer costs of data exclusivity were between \$ 6.3 m and \$ 22.04 m, and certain diabetes and heart disease products were 2 to 6 times more expensive than in Egypt, which still benefits from TRIPS flexibilities.³ The World Bank has studied the Thai HIV program and concluded that failure to use compulsory licenses could more than double the cost per life saved of its national program to distribute antiretrovirals.⁴

Developing nations and their advocates make a further criticism that is important to recognize, even though it is not directly a trade matter: this is that the patent system does not encourage research on those diseases specific to the developing world. There is little plausible profit and therefore basically no economic incentive to do research. This point was just made by the World Health Organization, which is fearful of the impact of stronger IP on public health. It has created a Commission on Intellectual Property Rights, Innovation, and Public Health, and recently formulated a research strategy for such diseases.⁵ The issue is being dealt with in many ways: through publicly sponsored and foundation sponsored research, and most recent through “public-private partnerships” in which both foundations and the pharmaceutical industry play a major role. But we do not yet have, for example, a malaria vaccine.

For HIV/AIDS in the low-income countries and particularly Sub-Saharan Africa, I think that the patent aspects of drug access are currently pretty much resolved. (I say “currently” because there may be new questions as second-line antiretrovirals become essential⁶). According to World Health Organization data, prices for antiretrovirals have

³ Oxfam International, *All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, (21 March 2007).

⁴ Ana Revenga et al, *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, The World Bank, 2006.

⁵ World Health Assembly, Global strategy and plan of action on public health, innovation and intellectual property, WHA61.21, 24 May 2008.

⁶ See C. Chien, HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare? *PLoS ONE* 2(3): e278 (March 14, 2007).

roughly halved between 2004 and 2007.⁷ The Campaign for Access to Essential Medicines claims even more dramatic declines – from \$10,000 to \$100 per patient per year between 2000 and now.⁸ In 2004-2006, generics supplied about 63% of the drugs for Sub-Saharan Africa at prices about a third of those charged by brand-name firms.⁹ In many respects, however, the real change here is less IP law than the rise of global donors who are funding the procurement of drugs. These include the Global Fund for Aids, TB, and Malaria (GFATM) and the U.S. President's Emergency Program for AIDS Relief Fund (PEPFAR). These entities have buying policies under which they will buy lower cost generics, rather than brand-name drugs under certain circumstances. The GFATM supports purchase of generics when they are legal in the particular country; PEPFAR takes into account whether the generic has been approved by the U.S. Food and Drug Administration. With these sources, supplied in part by generic manufacturers, together with the research-based industry's concessional supplies and with products produced under compulsory licenses in nations such as Brazil, the number of people receiving antiretrovirals in the low and middle income countries has risen from about 0.3 million at the end of 2002 to about 3 million at the end of 2007. This is still reaching only 31% of those who need the drugs;¹⁰ it nevertheless reflects an important achievement.

The area of current political tension is in the middle income nations. These nations are the growth pharmaceutical markets of the future, so that patent protection is of great importance to the future of the pharmaceutical industry's business model. At the same time, these nations still have many poor people and thus view themselves as reasonably benefiting from the Doha Declaration. South Asia, for example, has more very poor people than Sub-Saharan Africa.¹¹ Moreover, several, including Brazil and Thailand, have undertaken public programs to supply antiretrovirals to their HIV-affected populations, an expensive task whose overall cost depends heavily on the price of the drugs.

I believe that we must attempt new approaches in dealing with these nations. It is in our national interest to facilitate their growth in health. That may call for low, i.e., generic prices for at least some drugs for some people. This might be an exception for a limited time. In another approach, GSK is developing mechanisms for differential pricing within poorer countries based on charging a generic price to certain public or non-profit distribution channels while charging a higher research-reimbursing price to others.¹² Might the approach be extended? But there will need to be reforms beyond prices. For example, in a number of nations, including China, much medical care is effectively financed through pharmaceutical sales by doctors and hospitals – a process that certainly creates terrible incentives toward price markup to patients and toward

⁷ Data on HIV drug coverage from World Health Organization, *Towards Universal Access; Scaling up priority HIV/AIDS interventions in the health sector; Progress Report 2008*.

⁸ www.accessmed-msf.org/main/access-patents/introduction-to-access-and-patents/patents-and-access.

⁹ C. Chien, *supra*.

¹⁰ *Towards Universal Access, supra*.

¹¹ S. Chan & M. Ravallion, *How have the world's poorest fared since the early 1980s?*, (World Bank, Fall 2004).

¹² *GSK Corporate Responsibility Report 2007*.

overprescription.¹³ In India, the poor are not effectively served by the medical system. And some of these nations are pharmaceutical exporters at the same time that they have many needy citizens. Compromise seems reasonable; it will necessarily be more complex than a pure IP arrangement.

In approaching such a compromise, it is worth noting that price controls are likely to be the key topic for future international negotiations with developed nations in the pharmaceutical area. The importance of such controls is exemplified by the current European disputes over Roche's anticancer drug, Avastin,¹⁴ as well as by the inclusion of price-related provisions in the 2004 U.S.-Australia Free Trade Agreement and the great attention paid to the issue in the 2008 USTR Special 301 Report. Moreover, at some point, price controls will almost certainly be an issue in our own country – health care reform may increase the role of the government in purchasing pharmaceuticals, and it is hard to envision continued significant government purchasing of pharmaceuticals without pressure toward price controls. Unless the price controls are applied thoughtfully, the result will be to decrease incentives for research. Such harm may already have occurred in the U.S. childhood vaccine industry.¹⁵ In approaching health care reform and international trade both, we will need to define effective decision-making standards and procedures to maintain optimal incentives for research in medical technology.

These various trends suggest to me that it is important to moderate our IP focus and to recognize that IP is only part of a broader package of pharmaceutical trade goals. All nations want greater access to health care; all want to contain the cost of that health care; all want more advanced technologies. These are goals that have to be balanced; and the details of the balance may reasonably be different for nations at different income levels. Might we define a global vision that could be the basis of a new sectoral trade agreement governing a number of pharmaceutical issues?

Agricultural technology. Disputes over agricultural technology arose significantly earlier, in response to the developed world's efforts in the 1980s to encourage all nations to adopt plant variety or plant breeders' rights protection. These laws are a weaker form of IP designed to protect the products of traditional breeding. Their strengthening led to arguments that it was unfair to let developed nations protect bred varieties, while the genetic resources held in developing nations were freely available to the developed world breeder. These concerns contributed to the creation of the United Nations Convention on Biodiversity, a convention that has significantly slowed and complicated the scientific exchange of genetic materials.¹⁶ The developing nation's political mood in this area has been worsened by the grant of U.S. patents (probably improperly issued) over developing nation plants such as the 1997 patent on Basmati rice – grants the critics call "biopiracy."

¹³ Q. Sun et al, Pharmaceutical Policy In China, *Health Affairs*, 27: 1042-1050 (July/August 2008).

¹⁴ See, e.g., A. Jack, "Roche decision denies cancer drug to Britons," *Financial Times*, June 26, 2008, p. 3.

¹⁵ Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2004).

¹⁶ Sabrina Safrin, Hyperownership in a Time of Biotechnological Promise; The International Conflict to Control the Building Blocks of Life, 98 *American J. of Int'l Law* 641 (2004).

For the newer agricultural biotechnology, the most important issues arise under the regular patent law system. Developing nation patent laws are typically much less comprehensive and clear as to coverage than are U.S. and European laws; China's law, for example, is criticized in the 2008 Priority Watch List. On the whole, however, the concerns are not so much those of trade policy as those of the patent system itself, which, in the United States, reaches deeply enough into basic agricultural science to seriously complicate research. The majority of the breeding focused specifically on developing nations is carried out in the public and foundation sector including U.S. universities and the entities of the Consultative Group on International Agricultural Research (the CGIAR). The U.S. universities are bound by U.S. patent law and even some of the public institutions outside the United States often regard themselves as effectively bound by U.S. and European patents. Currently the public sector is coping through elaborate efforts to encourage the grant of private patent rights to developing nation use. For example, the African Agricultural Technology Foundation has been created by foundations and national foreign agencies to hold a portfolio of agricultural IP, and to supply that technology to Africa. Universities are organizing programs of humanitarian licenses to attempt to ensure that the technologies they develop are available to developing nations.¹⁷

Today's food crisis makes it imperative that these entities be able to continue to do research. Hence, I would strongly urge that developing nations be encouraged to design their patent systems to avoid patents on very basic scientific insights and to maintain broad and robust research exceptions, so that patents not be exercisable in a way that discourages others from the conduct of research. (There are parallel issues in the context of development of new drugs for diseases endemic to developing nations.)

The private sector is becoming extremely important in developing world agriculture. Thus, Monsanto has developed agricultural technologies used broadly in Argentina and Brazil, and India is one of the largest growers of genetically modified cotton. There, therefore, seems to be no reason for the USTR to refrain from encouraging protection of agricultural biotechnology in the more scientifically advanced and larger developing nations, but it is best to encourage it through arrangements that favor exclusivity in the marketing of specific products but allow great freedom of research.

The agricultural sector is like the medical sector in that the IP issues are only part of a much larger context, in this case, the regulation of genetically-modified organisms. Regulatory issues have been much more serious barriers to trade and research here than have IP issues. There is significant international dispute on the point, but, at least in my judgment, this technology can wisely make an enormous contribution to solving our food crisis. The USTR's efforts to encourage Europe to accept genetically-modified agricultural products are likely to benefit the entire world – many developing nations have been hesitant to accept such products and technologies either because of the European example or because they hope to export to Europe.

¹⁷ Amanda L. Brewster, Audrey R. Chapman and Stephen A. Hansen, Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation, *Innovation Strategy Today* (2005).

Climate change technologies. It is certain that there will be international technology transfer provisions as part of any follow on to the Kyoto Agreement on climate change. Understandably, therefore, there are already calls for a climate change analogue to the Doha Declaration. For example, last November, the European Parliament called for launching a study of possible amendments to TRIPS to allow “for the compulsory licensing of environmentally necessary technologies.”¹⁸

Based on my recent studies, this is probably not needed. This is not because there are not patents – there are many and there will be more – but because the effective royalties on patents in the climate change sector are likely to be small. This is because the competitive and industrial structures in the climate change sectors are radically different from those in the pharmaceutical sector. In the pharmaceutical sector, an individual product is often in a monopoly position, because it is the best available way of treating a particular disease. And the research costs are much greater than product production costs. Therefore, the markup on production cost can be substantial and can allow for broad differences in pricing in wealthy and poor markets. In contrast, in the climate change sectors, each technology is generally in competition with a number of others, and there are relatively competitive markets for the production of electricity and fuel as well as for such products as automobiles and housing materials. Hence, there can be only a small markup on the manufacturing cost. Research and development form a smaller portion of the overall product cost, and there is little room for differential pricing. Compare Merck, the U.S. pharmaceutical firm, and Vestas, the Danish wind turbine firm. Based on the most recent 10-Ks and annual reports, the 2007 cost of product for Merck is 25.4% of the sales price; for Vestas it is 83.0%, leaving a much smaller margin for research or for price reductions. It should also be recognized that for technologies like carbon capture and sequestration (CCS), the key markets are likely to be in nations like China and India; IP protection there is therefore crucial.

Before concluding, I should note that climate change may present many non-IP issues for trade negotiations. Unless we move to a large carbon tax, which seems politically unlikely, it is impossible to envision serious reductions in greenhouse gas emissions in any nation without a variety of subsidies and regulations. Will these arrangements be consistent with World Trade Organization rules?

Summary. In summary, I believe that it is the world interest and in our national interest to transfer technologies to the developing world in areas like medicine, agriculture, and clean energy. This reflects a humanitarian concern; it builds markets; and it contributes to building a world that is safe for all of us to live in on a long term basis. In all three of these sectors, the industries and markets are global, the cost of research is shared by public and private institutions, the expenditure and investment patterns are shaped by a variety of regulatory and pricing regimes, and the developing world’s access to innovation is beneficial to us. Each of the areas is best approached in a sector-specific manner that recognizes the role of IP without overweighting that role, and that seeks to structure the entire world research incentive system in a way that balances the need for innovation with the need for access to that innovation.

¹⁸ European Parliament resolution of 29 November 2007 on trade and climate change (2007/2003(INI)).

**INTERNATIONAL ALLIANCE OF THEATRICAL STAGE EMPLOYES, MOVING PICTURE TECHNICIANS,
ARTISTS AND ALLIED CRAFTS OF THE UNITED STATES, ITS TERRITORIES AND CANADA**

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July 11, 2008

The Honorable Max Baucus
Chairman, Committee on Finance
United States Senate
Washington, D.C. 20510-6200

Dear Chairman Baucus:

I wish to thank you for your invitation to testify before the Senate Finance Committee at a hearing to be held in Washington, D.C. on July 15, 2008 on "International Enforcement of Intellectual Property Rights and American Competitiveness".

Regrettably, I am unable to personally present testimony on that date due to a scheduling conflict, however, I appreciate your approval to allow the attendance and participation of IATSE International Vice President John Walter Cahill. Vice President Cahill will be prepared to testify at the hearing on my behalf.

I also wish to express my gratitude to the Senate Finance Committee on behalf of the members of the IATSE and the labor community as a whole, for the opportunity to bring to you the increasing challenges we are facing. Together, we can and will work towards enacting effective legislative measures to protect all those affected by the impact of Piracy, Intellectual Property theft and Copyright infringement.

Sincerely,

INTERNATIONAL PRESIDENT

TCS:dr

Enc.

cc: Members of the Senate Finance Committee



STATEMENT OF

Thomas C. Short
On Behalf of the

International Alliance of Theatrical Stage Employees,
Moving Picture Technicians, Artists and Allied Crafts
Of the United States and Canada
AFL-CIO, CLC

Before the
Senate Finance Committee

“International Enforcement of
Intellectual Property Rights and American Competiveness”

July 15, 2008
Washington, D.C.

Senator Baucus and Members of the Senate Finance Committee:

My name is Thomas C. Short and I am the International President of the International Alliance of Theatrical Stage Employes, Moving Picture Technicians, Artists and Allied Crafts of the United States and Canada, AFL-CIO, CLC. Although I am unable to personally be present to testify before you today, I am grateful that you have permitted me to provide testimony through my designee, John Walter Cahill who is an International Vice President of the IATSE. We truly appreciate this opportunity to set forth the plight of IATSE members, members of other unions and guilds in the entertainment industry.

The IATSE was founded in 1893 by a group of stagehands in New York City and has expanded throughout our 115-year history with local unions chartered throughout the United States and Canada. Today, the IATSE is the largest entertainment union in the world with nearly 120,000 members who are employed in legitimate theatre, motion picture exhibition, convention and trade shows, motion picture and television production, radio and television broadcasting and various other crafts of the entertainment industry. The mission of the IATSE is to provide the finest representation for our members and protect their best interests. In so doing, it is incumbent on the leadership of our union to negotiate with employers in a fair and equitable manner thereby obtaining the best possible wages and benefits for our members. The benefits we negotiate are critical to the times in which we now find ourselves with pension benefits being challenged by the adoption

of the Pension Protection Act of 2006 and the extreme challenges we face with the health care crisis in this country.

As it applies to benefits for our members, the issues of combating Piracy and Intellectual Property are of paramount concern to us. There are literally thousands and thousands of individuals employed in the entertainment industry. These are hard working people who do not earn millions of dollars to make one movie such as some of the high profile actors with whom most may be familiar. The relatively few actors who are able to command such wages are able to do so because of the box office receipts they secure. The glitz and glamour of the motion picture and television industry are the fantasies created on the screen. However, the number of individuals employed on the production of a given motion picture may be anywhere from 200 to 1,000 employees who are not in front of the camera and are working long, hard hours on a daily basis. The wages we have been able to negotiate for our members are perhaps higher than the minimum hourly wage. That said, our members may have to make their paychecks last much longer because these are not permanent jobs. They are jobs that will end when production is complete and the next job they get may not be for months.

Because of the nature of our business we have attempted to ensure that our members and their families are taken care of by securing additional revenue to be provided for them in the form of residual payments. In the IATSE those payments are contributed into the health and retirement benefits that our members so desperately need. Piracy is costing these individuals literally billions of dollars a year in benefit contributions. When

studios release DVD's to the market our members share in the profits of those sales with these residuals, however, when pirated copies are selling on the streets or being downloaded from the Internet, our members and many more workers see nothing.

What is piracy? Piracy is stealing, pure and simple. Anyone who sells, acquires, copies, or distributes copyrighted materials without permission is a thief. Downloading a movie without paying for it is the same as stealing a DVD off the shelf of a store. Making movies available on the Internet for downloading, selling pirated DVDs on the street, or taping (also known as camcording) and redistributing movies, live broadcasts or performances without a license are all forms of motion picture piracy. Downloading movies and music without the authorization of copyright holders is a growing international problem and we need to take action. It has been reported that camcorderd films in Canadian theatres account for almost 50% of camcord sources worldwide. The United States has been fighting back against camcording and 38 states have implemented legislation making camcording a crime.

This victimless crime mentality portrayed in an old-fashioned Hollywood movie is, unfortunately, how much of the public still perceives the illegal pirating of motion pictures, otherwise known as intellectual property theft. **PIRACY IS NOT A PETTY, VICTIMLESS CRIME.** It is not perpetuated solely by kids with camcorders and bargain hunters prowling the Internet. It is a devastating economic attack that, in 2007 alone, cost our industry \$6 billion! And, as large as that sum is, it's only a fraction of the \$250 billion that copyright piracy costs the overall U.S. economy every year. In fact, a recent study revealed that piracy in 2005 cost the movie industry

more than 141,000 jobs and \$5.5 billion in annual lost wages, while depriving state and local governments of \$837 million in tax revenue. That's money out of OUR POCKETS; money that could have gone toward roads, schools, and infrastructures to help shore up American communities.

Who does piracy hurt most? Working men and women of our union, who every year experience **roughly \$100 million in lost residuals to their health and pension funds** due to intellectual property thieves intent on copying, acquiring, and distributing copyright materials in an unauthorized manner. What can be done about piracy? Education for one: learning and recognizing what forms piracy actually takes. Some of the many examples include:

- Downloading movies from the Internet without making payment or without proper authorization of the copyright holder(s)
- Camcording movies in theaters
- Selling pirated DVD copies of films on the street
- Redistributing movies, performances, or live broadcasts without a license
- Making pirated films available for downloading on the Internet

While all consumers love something for nothing, the plain fact is that downloading a movie from the Internet without making a payment or without authorization from the copyright holder is no different than walking into a store and stealing a DVD off the shelf. Local and international law enforcement agencies have recognized that piracy is a serious CRIME. In 2006, the Motion Picture Association of America (MPAA) assisted law

enforcement agencies with operations in the Asia-Pacific rim that resulted in more than 30,000 cases of piracy. Nearly 12,400 raids were conducted, resulting in the seizure of more than 35 million illegal optical discs, 50 factory optical disc production lines, and nearly 5,000 optical disc burners. The net result of the MPAA's efforts was more than 11,000 legal actions against pirates in nations like China, Thailand, Malaysia, and the Philippines. Of the more than \$6 billion MPAA member studios lost to piracy last year, \$2.4 billion was due to bootlegging, \$1.4 billion to illegal copying and \$2.3 billion to Internet piracy.

Many city, state and federal agencies here in the United States are aggressively targeting American-based piracy. New York City signed into law a Bill that upped the ante against pirates videotaping movies in theaters in their five boroughs. What was once a \$250 fine and 15-day jail sentence in New York City now means six months in jail and fines up to \$5,000. More recently, legislation was passed on New York's State level that criminalizes piracy with penalties for felony. Likewise, for a joint marketing campaign by the MPAA and the National Association of Theater Owners (NATO), whose "Lights. Camera. Busted." posters, displayed in movie theaters around the country, remind would-be thieves that camcording is a federal offense, resulting in jail time and fines of up to \$250,000! Underscoring the anti-piracy movement is the fact that legislation has been enacted in 38 states, making camcording illegal. Our industry, which accounts for 1.3 million jobs and \$10 billion in federal and state taxes per year, cannot find itself commanding any less attention than a Wal-Mart or a General Motors. The entertainment industry is no corner candy store, and motion picture pirates are not a scruffy gang of teenagers looking for kicks.

PIRACY has become a highly evolved, criminal enterprise that is robbing billions from our industry. It is the THEFT of someone else's PROPERTY, and robs from those who work the hardest in the industry: IATSE craftspeople. Be aware and be informed. Protecting the motion industry benefits everyone.

What can we do?

First, we need to educate ourselves, our families, and our friends. We need to stop the theft we know about. We need to recognize piracy and who it actually hurts and inform those around us about the facts. Just as this society punishes bank robbers, this society should punish with just as much force those pirates who rob us.

Second, from our elected leaders we seek support and sponsorship of stronger legislation protecting intellectual property. We have the obligation to work with them to strengthen existing laws and enact new laws that protect us. After all, the movie industry is a significant portion of the economy: it accounts for about 1.3 million jobs, pays \$30.24 billion in wages, and pays \$10 billion in federal and state taxes a year. We all benefit from a thriving movie industry. The loss of \$6 billion in one year to piracy is unacceptable.

Six billion dollars in one year is an outrageous amount to have stolen from the pockets of the hard working employees who toil every day to make stories come alive on the big-screen. You see, the majority of the workers hurt by piracy are not the big-name actors or the wealthy producers—they make up only a small percentage of the motion picture workforce. The

people who are hurt the most are the ones working behind-the-scenes: us—each and every one of our members.

The IATSE consists of members in both the United States and Canada and our Canadian brothers and sisters are seeking relief from the Canadian government in the form of anti-piracy legislation as well. Our neighbors north of the border are under siege as well. Canadian movie theaters account for nearly 50 percent of all camcorder sources worldwide, and Canada's film industry has come out swinging. Amendments to Canada's Criminal Code were passed by the House of Commons in the 1st Session, 39th Parliament in 2006, which made individuals videotaping a movie, without the consent of the theater manager, subject to 2 years in prison; videotaping, without the consent of the theater manager, for the purpose of sale, distribution, or commercial transaction, now lands pirates 5 years in prison.

In addition, there is currently an initiative led by the Canadian Motion Picture Distributors Association (CMPDA – the counterpart to the MPAA in the U.S.) and other industry stakeholders to support recent tabled amendments to the Copyright Act in Canada. The IATSE and others will participate with the CMPDA in their Initiative to support Bill C-61, An Act to Amend Canada's Copyright Act. In brief, the proposed legislation is similar to the U.S. Digital Millennium Copyright Act (DMCA); it would go a long way to tightening up copyright protection and allow Canada to meet its obligations under the World Intellectual Property Organization (WIPO) treaties.

In the United States we are seeking relief on all levels of the legislature. This includes individual States, the U.S. Senate and House where we have been successful thus far in bringing to the attention of our elected leaders the effects of piracy, theft of intellectual property, and copyright infringement. We have recently seen legislation passed in the State of New York which provides the penalty of a felony for piracy. States across the nation are taking a look at what can be done to combat this crime. We are working with various entities to jointly protect workers from these crimes.

The entertainment industry is the largest export of product of the United States and is an area in which our economy thrives. It provides revenue for our government and employment for a vast number of U.S. citizens. We must collectively take strong action against this problem as expeditiously as possible.

Motion picture piracy is not something we can ignore. Piracy is a serious crime. We in the IATSE, our union brothers and sisters, and about a million hard working men and women, are its victims.

On behalf of the IATSE, I am particularly appreciative of this opportunity to have testimony presented to you and I thank this Committee for inviting us to participate in your hearing and provide information we feel is important for you to know and consider when legislation is to be formulated, proposed and acted upon.

If the IATSE can be of any further assistance to this and other committees regarding this issue, we stand ready, willing and able to do whatever we can to protect our members and workers across this nation.

Thank you.

Testimony of Jeff Kindler
Chairman and CEO, Pfizer, Inc.,
Before the Senate Finance Committee on
International Enforcement of Intellectual Property Rights
And American Competitiveness
July 15, 2008

Thank you, Chairman Baucus, Senator Grassley, and the entire Finance Committee for inviting me here today.

I'm Jeff Kindler, the Chairman and CEO of Pfizer, Inc. The issue you consider today has interested me for a long time. It is – of course – a vital concern for my company.

Mr. Chairman, you and this Committee have championed both the urgency of meeting the challenges of global competition, and the ways that we can overcome them. I welcome this chance to talk about those issues.

Intellectual property has been valued by Americans since well before 1787, when our founders wrote a Constitution empowering Congress to write laws protecting patents and copyrights to promote innovation.

A quarter century later, in 1814, Dr. William Thornton -- the designer of the Capitol -- watched invading British troops burn the White House, and then turn their guns on the patent office.

"Are you English or vandals?" he is supposed to have said, planting his body in front of the British guns. "This is the depository of the ingenuity and inventiveness of the American nation."

The British didn't fire. And Thornton was right. In fact, the history of patents is the history of the world's "ingenuity and inventiveness."

And it is more. Because over the centuries we have seen this:

- The protection of intellectual property - IP - equals innovation.
- Innovation equals competitiveness.
- Competitiveness equals jobs.

I certainly see this at Pfizer. We're the largest pharmaceutical company in the world. Our 85,000 employees are dedicated to inventing, developing, making, and providing to patients and their physicians medicines—medicines that prolong lives, improve lives, and save lives.

Recently, Pfizer scientists invented the first new drug in a decade to help people stop smoking. We make medicines that shrink tumors for patients with kidney cancer, ward off depression, relieve the pain of fibromyalgia, lower cholesterol, and treat many, many other serious medical conditions.

At the heart of our enterprise is scientific discovery and invention. And I invite all of you to visit the thousands of scientists working at our laboratories in Connecticut, Missouri, Massachusetts, California, and other places around the nation and the world. You'll see firsthand the passion of those who want nothing more out of life than to find cures for Alzheimer's, or cancer, or diabetes or any of the other medical discovery projects for which we invested \$8.1 billion in 2007.

Not that Pfizer is unique. American's innovative bio-pharmaceutical industry spent almost \$60 billion last year researching the unmet medical needs of patients around the world.

Our ability to make these investments, to hire the scientists, and spend the enormous resources necessary to invent new medicines depends entirely on our ability to preserve strong intellectual property protections for those inventions. These inventions are very risky and very expensive. Even after years of research and the investment of many hundreds of millions of dollars, it is very rare for a compound discovered by pharmaceutical scientists to get to the market and become available to patients. On those rare occasions, we must be able to protect that invention as our intellectual property for a limited time, before it becomes, in essence, public property.

In short, intellectual property is the foundation of our ability to discover and develop innovative new medicines.

Today's hearing focuses on competitiveness.

I'd be remiss if I didn't mention the broader picture. For the pharmaceutical industry we face challenges to our ability to innovate that go beyond intellectual property protection, both abroad and in the United States. In many ways, we see the environment for innovation in the bio-pharmaceutical sector getting tougher: more onerous restrictions and requirements from payers, higher regulatory hurdles, both before and after drug launch, and increasing and costly patent litigation. I do not mean to say that the policy aims behind these measures are illegitimate; only that industry, the public, and policy makers need to work together to address issues in a way that does not undermine incentives to develop new treatments and cures. Above all, we need to keep in mind the impact these developments have on patients.

These broader issues deserve much more attention. Today, I would like to focus on the critical importance of intellectual property protections.

There are some who dispute the value of IP. I recommend to them – and this Committee – the recent study Bob Shapiro and Nam Pham performed for World

Growth, a non-profit organization that is dedicated to increasing resources available to disadvantaged populations to improve health and economic welfare.

Shapiro and Pham point out that these days almost two-thirds of the assets of top U.S. companies are not physical. They are not factories or trucks. They are ideas. And that means chiefly ideas protected by patents and trademarks.

Economists often use the amount of R&D to determine which companies are IP-intensive. The Shapiro and Pham study found that of all the industries in the United States, the pharmaceutical industry spends the most – about \$70,000 per employee.

Commenting on the study, Princeton professor and former Federal Reserve Vice-Chair, Alan Blinder wrote, “To a remarkable degree, America’s most productive manufacturing industries are the ones that invest the most in R&D.”

I agree. In fact, there’s a striking difference between salaries in IP-intensive states – like Colorado, Arizona, Massachusetts, or Michigan – and states that are less IP-intensive. The industries that spend a lot on R&D create jobs. And in our industry we create good jobs—well-paying, high-technology jobs.

This is an era in which high-tech jobs have been America’s competitive advantage. Eighty percent of American jobs now require education beyond high school. And among the 500,000 jobs the pharmaceutical industry contributes to the American economy, you’ll find 80,000 of the world’s most brilliant scientists.

And jobs are not the only economic advantage of protecting the IP of medicines. Strong intellectual property protection creates the necessary incentives for biomedical research. And the more biomedical research and development, the more medicines we develop and the better our society will be. Two economists from the University of Chicago estimate that a 10 percent permanent reduction in deaths from cancer would be worth more than \$4 trillion in the United States alone.

Of course, we don’t measure what we do by numbers alone. We measure it by the huge reduction in human suffering we help to produce. And so, for example, one of the most exciting things I do is talk to our scientists about the discoveries and inventions that they are pursuing. This is particularly exciting in a year like this one, in which Pfizer has increased the number of cancer R&D projects in our pipeline by 400 percent.

All of this represents the economic and human potential produced by a reasonable tax system, a trained workforce, government support for basic science – and a strong tradition of IP protection.

As Blinder summarizes in the World Growth study’s conclusions: “U.S. policymakers should foster the creation of more intellectual property and work hard to protect the IP that American companies already have.”

My company and our industry stand poised to continue – as we have for decades – to make an enormous contribution to the prosperity and well-being of American citizens – and to the health and welfare of people all over the globe.

That includes people in developing countries where booming economies have made it possible for hundreds of millions of patients to use the medicines we develop in places like Groton, Connecticut; St. Louis, Missouri; Cambridge, Massachusetts; and Northern and Southern California. Right now, half the revenue for the pharmaceutical industry comes from the United States, about a third from Europe and Japan – and only 13% from the rest of the world.

That is changing. Fast. By 2050, drug sales will be larger in Asia than in any other region in the world.

Meanwhile, the aging populations that all countries are experiencing will present new medical challenges.

Solving these kinds of problems is what we do. Of the 300 products on the World Health Organization's Essential Drugs List, virtually all came from the labs of the private sector, R&D based pharmaceutical industry.

That includes all 10 of the 10 leading drugs for cardiovascular disease – a disease that kills three of every 10 people in the world.

It includes all 10 of the 10 leading drugs for mental illness. All 10.

It includes all 10 of the 10 leading drugs for respiratory disease like asthma – which kills almost two of every 10 people in the world.

These medical innovations – and the lives they save and extend – would simply not be possible without research-based pharmaceutical companies like ours making the huge investments and taking the huge risks that the development of modern medicines requires.

And making those investments and taking those risks would simply not be possible if inventors weren't assured their intellectual property would be protected.

This is the incentive this American tradition has produced.

So it is troubling to have to tell you that we meet at a time in which respect for intellectual property rights has eroded around the world, including – I'm sorry to say –, here in the United States where it has been part of our traditions since before the Constitution was drafted.

That's not just true in the pharmaceutical industry. We see it in the pirated recordings and DVDs for sale on street corners in Bangkok, Buenos Aires, or Jakarta. We see it in

rampant software piracy, and in counterfeit manufactured goods, like auto and even airplane parts.

We see it in the arguments raised against patents and against protection of content by groups that may be well-intentioned but misunderstand the basis of innovation and the problem of access to medicines.

We see it in the proliferation of counterfeit medicines and other products on the Internet.

We cannot permit a culture of disrespect for these property rights to take root and grow.

We must be vigilant.

Ultimately, weakening a right that has been a part of our legal system for so long will mean fewer American jobs in Montana, Iowa, West Virginia, Utah, North Dakota, and in every state of the Union.

But it will not only hurt America. It will damage prosperity, health, and progress everywhere on every continent, and in every country where creative solutions matter.

What kinds of threats do we face? There are at least three:

- **The growth of counterfeiting**
- **The assault on patents**
- **The failure of foreign countries to reward innovation properly**

Let's take them one by one.

COUNTERFEITING

It is not a new problem. But it has exploded with the rise of the internet. Six out of every ten pills sold online are fakes. In Europe, counterfeiters have learned they can make more money selling fake versions of legal pills than they can making even some illegal drugs.

Counterfeiters produce fakes of nearly all Pfizer's best-selling medicines. That's probably true for all U.S. pharmaceutical companies. But Pfizer's Viagra is the most counterfeited drug on earth, with losses to counterfeits estimated at \$2 billion per year, significantly more than last years' Viagra sales of \$1.8 billion.

This is a serious problem not just for the companies, but also for patients. When they order drugs from the Internet, they think they are importing them from qualified manufacturing plants. They may think they're taking drugs made by Pfizer. Too often,

counterfeiters have concocted them in a dirty basement somewhere in a part of the world that lacks the strong safety system of the United States.

What looks like the real thing may contain ingredients that at best don't work. That means patients don't get the medicines they need for cancer, diabetes, or other serious ailments. That means counterfeits hurt the reputation of my industry – as patients wonder why a pill that says Pfizer or Merck or Lilly on it doesn't seem to work.

But far worse, sometimes counterfeit medicines contain ingredients that can injure or kill – as happened this year when Chinese counterfeiters adulterated heparin supplies with a shellfish derivative that made almost 800 Americans violently sick.

This is by no means a problem just for the United States. The WHO estimates thousands of patients around the world have become ill or died as a result of fake medicine.

What do we do about counterfeiting? First, we should continue to attack counterfeiting overseas by making sure our trading partners are serious about cracking down more vigorously on the manufacturers and purveyors of false medicines.

The "Special 301" process, in which the U.S. Trade Representative annually names the worst global IP offenders, is helpful in this regard, but we should strengthen the consequences for countries that continually end up on the Special 301 watch lists.

Right now, a country suffers some loss of prestige when it is named as an offender. Adding more teeth to Special 301 would give these countries a greater incentive to stop counterfeiting. We can use not just sticks but carrots – training and cooperation – in this effort.

Second, we should do more to stop counterfeits from entering the United States. For this, there needs to be greater cooperation between the FDA, Customs and Border Protection, and other agencies charged with stopping fraud and importation of unregulated drugs through our borders.

We cannot allow a country that has led the way in finding medicines that are safe to fall prey to those who make money putting Americans in danger.

PATENTS

The global assault on patents is also not new. In what I believe is a misguided effort to achieve the worthy goal of increasing access to drugs, some activists have argued for years against patent protection for pharmaceuticals.

Meanwhile, some developing countries see the suspension of IP as a short-cut to development, even if it undermines innovators in our country and in theirs. For Pfizer

and many other companies, the large emerging and middle income countries – such as China, India, Brazil, and others, represent a critical opportunity for future growth, as income and demand for quality health care grows. Given the competitiveness of our industry, this is an opportunity to create thousands of good new jobs here. But that opportunity will be lost if these countries flout our intellectual property rights.

That is why we were so concerned with two developments in 2007.

First, the May 10, 2007 Agreement on trade. In it, Congress and the Administration agreed to strengthen the labor and environmental provisions of Free Trade Agreements as well as several other changes to FTAs, in order to make them acceptable to more members. We, like many others, want to move the trade agenda forward, and we take no issue with many provisions of this agreement. But we believe that weakening IP rights for our sector is the wrong way to advance the trade agenda. The May 10 agreement changed the text in ways that made it more difficult to compete in three areas. I believe they were totally unnecessary, given the reality of the marketplace:

- **Data exclusivity:** In many countries where patent protection is not robust, we rely on that period of exclusivity. The May 10 agreement shortened it. In Colombia, for example, we are still waiting for patents to be registered on many of our leading products, such as Lipitor, Celebrex, Sutent, Maraviroc and Viagra. Data exclusivity, which prevents generic companies from using our test data to obtain marketing approval, is the only effective protection we have in that country. The same is true of many other markets for which this may set a precedent.

The notion that data exclusivity in itself somehow unfairly stunts the growth of generics is simply wrong.. Case in point: Colombia. The generic industry has flourished since data exclusivity was put in place in 2002 – from 65% to over 70% of the market.

- **Patent linkage:** Drug regulators in some markets often grant marketing approval to generics while our product is still on patent, simply because they do not check to see. In Peru, 17 generic versions of Lipitor were approved after our patent was granted – and several while it was still pending. The new agreement weakens this simple check and replaces it with a more cumbersome process to keep generics off the market when there is a valid patent.
- **Patent term extension:** If there's an unreasonable delay in the grant of market approval, we need a way to make up for it. The agreement made that optional for these countries. As already noted, in Colombia and many other countries, we can wait a decade or more to even get a patent registered, running out the clock on our patent life.

Perhaps most disturbingly, the dilution of IP that resulted from the May 10 agreement applies only to pharmaceutical products.

Why should intellectual property for medicines be subject to a different, less effective set of rules than the ones that govern inventions in every other industry?

All of these reductions in IP protection for medicines that resulted from the May 10 agreement were the result of a unilateral decision by the United States, *after* the countries involved had already agreed to a stronger standard of IP protection. It is beyond me why our country, with its centuries-old tradition of recognizing the importance of IP rights would dilute IP protections in other countries that were willing to strengthen that protection.

At a time when we need to strengthen intellectual property protection around the world, this sends the wrong message not only to our FTA partners, but also to other developing countries who will interpret it as a signal from our government that they too can weaken their IP protection. And what message does it send about how we value IP here in the United States?

A second important and worrisome development last year occurred when the military government of Thailand issued compulsory licenses—CLs—to its own Government Pharmaceutical Organization on a variety of medicines.

A CL allows a country to use a patent without the patentholder's permission. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) permits such a step in certain circumstances. At Pfizer, we fully support the TRIPs flexibilities, and we share the goal of facilitating access to medicines to the most needy. But resorting to compulsory licensing as a routine matter of public policy is not the best way to achieve this goal. We emphatically disagree that the existence of IP is the major impediment to access to medicines in most cases and, therefore, suspending those rights should be considered only rarely.

The specific circumstances in which we believe CLs can be justified are:

- **An Urgent Situation:** Unexpected, widespread or quickly spreading communicable illnesses, where urgent access to medicines is critical to maintaining public health, and when other more constructive solutions cannot be agreed upon for receiving immediate supplies.
- **Demonstrated Relevance and Lack of Access to Patented Medicines.** Situations in which a) medicines under patent are critical to addressing the public health emergency, and that b) they cannot be accessed from the originator or right-holder through good-faith negotiations.
- **Lack of National Resources.** Situations in which national resources are lacking to access the patented medicines from the rights-holders under normal market

conditions. This would generally not be the case in most “middle income” countries, or countries like China with substantial foreign exchange reserves.

On the other hand, countries should not resort to CLs as a budget mechanism -- simply to save resources that are spent on other areas of the national budget; in my view, using CLs to advance budget priorities other than health is not enough to justify abrogating IP.

We must, of course, help suffering people in the developing world. And, at Pfizer, we do. We invest substantial human and financial resources in our programs supporting AIDS service organizations, in the Global Health Partnerships we've launched to fight cancer and tobacco addiction, and with our Global Health Fellows who volunteer around the world in refugee camps, Tanzanian villages, and clinics in Eastern Europe.

But the solution to these problems is not simply to give away the rights to our inventions. In public health emergencies, quick access may take precedence. But an arbitrary suspension of IP whenever it suits a domestic interest? That's not appropriate. We don't force Detroit to give away its cars for free; we don't force farmers to give away their corn and wheat; and we certainly shouldn't force American inventors to give away their inventions either.

We agree with EU Trade Commissioner Peter Mandelson. He recently wrote that systematic resort to CLs could undermine innovation and the development of further medicines.

In Thailand, the criteria for CLs did not apply. We saw for the first time a country create a program of issuing multiple compulsory licenses – and announce its intention to keep doing it. Moreover, they did it not to help patients but to create competitive advantage. They assumed for themselves the right – simply put – to take someone else's property – their intellectual property – whenever they choose. In what other circumstances would we find this acceptable?

Such a strategy if it became common would deprive us and countries like Thailand of the new – and better – versions of the drugs they need.

It would be a classic case of killing the goose that laid the golden eggs.

And it would be just the beginning. For anti-IP activists have found new targets like green technology.

They argue that improving health and halting climate change are issues so important that we should not be hindered by IP protection in seeking to address them.

Inventions in these areas, as in pharmaceuticals, are incredibly important. But since when have Americans felt IP protection is important only for trivial discoveries?

Isn't IP protection even more essential to provide incentives to pursue discoveries and inventions addressing our most important issues—like health and the environment?

Such incentives were very real for Alexander Graham Bell, Thomas Edison, and Philo T. Farnsworth.

Senator Hatch knows that last name. The statue of Farnsworth in the Capitol in Utah's way of honoring the Utah farm boy who invented television as a teenager – and who is not a household name because his intellectual property did not get enough protection.

Precisely because they *are* so important, we need more IP protection for innovation in health and the environment – not less. And we need more, not less, investment in new discoveries in these areas.

Much of the debate over the Senate's recent global climate change bill focused on the green jobs that bill would create in the United States

But if we allow CL use in all cases without consequences, why can't China, India, or any other country simply take U.S. technology to meet their emission goals? We've now permitted the precedent. If we continue to tolerate it, we will have ensured those green jobs just won't materialize – at least not in the United States.

Not just for my industry, and not just for those of others seated at this table, but for inventions yet unimagined – we must preserve strong patent protections.

The key to better health in the developing world is not to destroy patents – but to create partnerships aimed at improving the public welfare.

REWARDING INNOVATION OUTSIDE THE UNITED STATES

Around the world, countries rely on U.S. pharmaceuticals to keep them well and cure them when they're sick.

That's obviously good for Pfizer.

But it is also good for Americans. And it hasn't happened by accident.

In fact, the story of innovative medicine is really two stories—one in Europe and one in the United States.

In Europe, a generation ago, vibrant, competitive pharmaceutical industries flourished in France, Germany, Switzerland, and a host of other nations.

But these systems, forced to cut short-term costs, ended up offering insufficient rewards for innovation. In 2004, the U.S. Commerce Department completed a study

demonstrating that price controls and other restrictive practices in Europe and elsewhere stifled innovation. While these countries seemed to offer formal protection of IP, such as patents, the range of other public policies effectively undermined those protections. As a result, the pharmaceutical industry in many of these countries has withered.

Recently, two Italian researchers looked at innovation and industry in Europe. They compared U.S. and European innovation systems, hoping to advance a concrete agenda so Europe can regain competitiveness in pharmaceuticals.

Their conclusion: "Europe is lagging behind the U.S. in its ability to generate, organize, and sustain innovation processes in pharmaceuticals."

In the United States, in contrast, a number of factors have combined to create success, including policies made here in Washington: wise federal investment in basic research; close collaboration between public and private researchers and the willingness to preserve incentives for intellectual property. These elements represent the fundamental foundation of an economic and innovation system that we should preserve.

But there's an important drawback to the differences between our approach and that of many other nations around the world.

It means that, in part, U.S. consumers have disproportionately subsidized the costs of biomedical research and development for patients all around the world.

And, so, I hope we not only preserve intellectual property rights at home, I hope we work hard to foster them abroad. That's why Congress's decision to dilute IP protections, which some countries had themselves agreed to in some recent FTAs, is so disappointing.

OPTIONS FOR CONGRESS.

So, in working to defend IP protection around the world, what specifically can Congress do?

Let me offer a few suggestions:

STRONGER ENFORCEMENT TOOLS: U.S. officials need to hold the worst counterfeit offenders accountable, and the government needs more resources to do that. The global IP problem is growing faster than the capacity of our agencies that fight it.

STRONG, ENFORCABLE IP PROVISIONS IN OUR TRADE AGREEMENTS: This means for all forms of IP. The global landscape for IP is evolving. Our trade agreements need to reflect those changes. Acquiescing to a weakening of IP in these agreements will mortgage our economic future and global competitiveness.

Congress should act on strong trade agreements that include important improvements in IP – like the FTA with Korea – as soon as possible.

A NEW ANTI-COUNTERFEITING TRADE AGREEMENT: Such an agreement with our most advanced trading partners will set a global benchmark. Critical as well: stronger border measures to combat counterfeiting, as proposed in pending legislation.

EXPANDED DATA EXCLUSIVITY: Right now our major trading partners have longer periods of exclusivity than we do. There are those who would shrink ours. I believe we must expand those protections in order to stay competitive with countries that, in this respect, have stronger IP protections than the U.S.

CONCLUSION

A final point:

The environment surrounding the pharmaceutical industry has changed. The industry has changed with it. We are moving from one that has too often reflexively fought government to one seeking partnership. We have this year for example, indicated our desire to work constructively to support SCHIP legislation, HIV/AIDS assistance through renewal of the PEPFAR program, and Trade Adjustment Assistance legislation.

This record makes me confident that we can approach all the issues surrounding public health as partners.

And an essential building block to collaborating on all of those issues is the issue we discuss today: the need to preserve intellectual property rights.

For the threat to IP around the world is real.

We need to fight for it in our trade agreements.

We need to fight for it in our battles against counterfeiters.

We need to fight for it in our diplomatic efforts.

In mounting that fight, history is on our side. Dr. Thornton was right. After almost two hundred years we still see the ingenuity and inventiveness of this country written in those records in the Patent Office.

We must make sure that those who don't see it, train their guns somewhere else – and that a policy that has served us so well in the past guides us again as we move into the future.

Thank you.

Testimony of Andy Lack
Chairman, SONY BMG Music Entertainment
before the Senate Finance Committee on
International Enforcement of Intellectual Property Rights
and American Competitiveness
July 15, 2008

Good morning. My name is Andy Lack, and I am Chairman of SONY BMG Music Entertainment.

Thank you for the opportunity to address the Committee on the issue of intellectual property protection in global markets. I commend Chairman Baucus, Ranking Member Grassley, and the members of the Committee for recognizing that this issue is of great importance to the entire U.S. creative community, as well as to the U.S. economy and to U.S. society as a whole. This Committee has been a tremendous champion for strong and effective copyright protection in global markets, and I thank you for your leadership.

Sony BMG is a recorded music joint venture that operates in more than 40 markets around the world and employs approximately 2300 workers in the United States. Headquartered in New York, SONY BMG is one of the four major record companies in the music industry. I think it's worthwhile to highlight that, even though SONY BMG is a global company with integrated interests in all facets of the music business, ultimately our assets are thoroughly intangible because they are based in the creative work of the artists themselves. For this reason, economic survival in the music industry is reliant upon the adequate protection of intellectual property.

The stakes for our national economy are high. It has been reported, and the Administration has so testified before Congress, that roughly 40% of the U.S. economy is dependent upon IP protection in one way or another, and the core copyright industries are alone responsible for an estimated 6% of U.S. GDP. But the continued growth of this vital economic sector is seriously at risk. This Committee has highlighted the importance of the global fight against piracy, and we need your help now more than ever. My industry's story is but one, yet it is telling: While people listen to more music today than at any point in recorded history, paid consumption is sharply down, as piracy and the acquisition of music through illegal channels continues to skyrocket. Creating opportunities for business growth is critical to ensuring the survival of one of the world's most vital, diverse and competitive industries.

The record industry currently faces a piracy phenomenon on two fronts. One involves the physical marketplace, in which we confront increasingly organized and multinational criminal enterprises involved in massive production and trafficking of pirate CDs and other optical media. The second front of the piracy war exists in the online marketplace. Here, too, global criminal organizations are engaged in illegal distribution directed at generally law abiding citizens who, in the privacy of their own homes, are now actively involved in trading or sharing unauthorized recorded music files. It is necessary that any global IP protection regime address the piracy problem on both the physical and digital fronts.

Music companies are not alone in confronting the pernicious threat of counterfeit products and digital theft. A coalition spearheaded by the U.S. Chamber of Commerce and the National Association of Manufacturers, The Coalition Against Counterfeiting and Piracy (CACAP), has highlighted the broad scope of the threat that counterfeiting and digital theft poses to the U.S. across more than two dozen sectors of the U.S. economy. The Coalition has emphasized that the threat from counterfeiting and digital theft robs the U.S. economy of hundreds of billions of dollars of GDP and hundreds of thousands jobs, threatens health and safety in many sectors, and is driven by organized crime.

SONY BMG has employed a multi-pronged strategy to address these challenges. First, we are expanding legitimate avenues for digital distribution through creative new business models and experimental licensing arrangements. Second, we are educating the public and our industry partners about the risks involved with piracy and steps they can take to curb infringement. And, finally, we are taking enforcement actions against infringers, and against services that effectively encourage or induce infringement.

However, a company like SONY BMG, and copyright industry bodies like RIAA, cannot fight piracy on our own. Today's pirates often operate through multinational criminal syndicates simultaneously involved in replication, printing and distribution around the globe. They rely on traditional means of avoiding punishment such as bribery and other forms of corruption, but also have new tools in their arsenal that increase their stature -- force and other threats of violence, and the ability to rapidly change the location of the various components of their enterprises when confronted with governments prepared to tackle piracy issues. Pirates actively seek out jurisdictions in which either the law, lax enforcement of the law, or the general inefficiency and corruption of the judicial system, offer relative safety for their operations. Company representatives and counsel have in some countries already experienced threats on their lives or physical intimidation when their investigations began to make progress. In some cases, this has prevented any enforcement activity by the private sector.

We therefore look to the U.S. Government for leadership, at home and in bilateral and multilateral settings, to keep intellectual property protection at the top of the enforcement agenda and ensure that law enforcement agencies have the necessary tools and underlying legal framework to accomplish their goals. Adequate enforcement requires adequate resources, and to that end we believe that law enforcement must have dedicated personnel who are focused on seeking out and stopping illegal trafficking in pirated goods. The U.S. Government should encourage countries with existing organized crime laws and investigative procedures to bring them to bear against syndicate operations involved in piracy. And where such laws and procedures are not in place, the U.S. Government should encourage governments to adopt them and to include, among predicate offenses, intellectual property rights violations.

Aggressive and constant monitoring of the implementation of bi- and multilateral trade agreements by our trading partners to ensure compliance is of paramount importance, and we salute the work that USTR, working with other U.S. Government agencies, does in this

regard. We also applaud the U.S. Government for the actions it has taken to make China accountable for its piracy problem, specifically through the filing of actions at the WTO.

Congress can continue to play a role in helping to ensure that our trading partners meet their obligations to provide adequate and effective copyright protection by holding oversight hearings such as this, by ensuring that the Administration has adequate resources to safeguard this unique American asset, and by ensuring that all trade programs provide maximum leverage to require beneficiary countries to provide effective copyright protection. Unilaterally extended U.S. benefit programs crafted by Congress continue to play a key role in providing incentives to countries to meet their IPR obligations.

This Committee should also continue to pay close attention to Russia's accession to the World Trade Organization (WTO). The Russian government wishes to join the WTO; however, to date they appear unwilling to take sufficient actions against rampant copyright piracy as they are required to do by the bilateral IPR agreement concluded between Russia and the United States in November 2006. We strongly advocate that the U.S. Government not complete the WTO accession process with Russia until Russia takes actions that effectively address this critical problem. There have been some promising developments in Russia, but compliance with the bilateral agreement that has been called the "roadmap to WTO accession" has not yet been achieved. We are particularly concerned by the lack of government action against the individuals responsible for allofmp3.com and other similar online sites, and against the rogue licensing societies that purported to grant licenses for content that they did not control.

SONY BMG, in line with the industry as a whole, has been adapting our business to the dramatic changes brought about by the digital age. In the US, only five years after the music download business first emerged in a commercially meaningful way, 23 per cent of all recorded music sold is online or mobile. Record labels are becoming broad-based entertainment companies, developing new revenue streams. The consumer has better choice, availability and flexibility in enjoying music than ever before. Our digital revenues are growing and diversifying as our business model changes from one dominant format to hundreds of channels and products.

However, while broadband Internet access offers exciting prospects for the legitimate dissemination of copyrighted materials of all kinds, too often high-speed Internet connections are being used to distribute unauthorized copies of sound recordings, software, videogames, literary material, and motion pictures. The unprecedented growth of the Internet and increased availability of broadband connections, coupled with the absence of adequate copyright law and/or enforcement in the online environment in many countries, has provided pirates with a highly efficient distribution network to reach the global market. Pirates offering and distributing infringing product can now reach any part of the world with ease, regardless of where they are physically located. Consequently, the U.S. copyright industries face the daunting task of trying to enforce their legal rights in an online world where borders and distances have decreasing practical significance, and where anonymity is claimed.

What tools do we have to address this type of online piracy where legal action by the industry does not suffice? First, of course, we have the framework of international trade law discussed above. But industry and government must also work together to address the particular legal and technological challenges of the electronic marketplace.

The so-called WIPO Internet treaties adopted in 1996 set the stage for fair international digital distribution of music. These treaties represented significant and necessary improvements in the international legal structure. Of greatest importance, the treaties made it absolutely clear that copyright holders are permitted to control the electronic delivery of their works to individual members of the public. This both anticipated and responded to the realities of the electronic marketplace, where copyright owners rely increasingly on electronic delivery to meet consumer demand. This level of copyright protection, in conjunction with technical protections (also addressed in these treaties), is key to encouraging copyright owners to make their works available through these new media.

It is critical that the marketplace, with government support, continue to develop its own solutions. To that end, SONY BMG and other content companies have begun to engage in a dialogue with our industry partners to find new ways to cooperate in the fight against piracy. In particular, this past year has witnessed a virtual explosion of global public interest in developing structures in which Internet Service Providers (ISPs) can enhance their role in addressing the unauthorized transmission of copyright content. This is an important development, because until now ISPs have not adequately responded to the massive theft that is occurring through their networks.

Today, however, a shift is underway. The content community, governments, consumers, and ISPs themselves are beginning to respect the notion that the carriers of digital content must play a responsible role in curbing the systemic piracy that is threatening the future of all digital commerce. Industry has been hard at work on these critical issues, but we need the help of the U.S. and foreign governments to make the Internet safe for e-commerce in copyrighted material by encouraging marketplace solutions to take hold.

Furthermore, renewed emphasis on law enforcement training is vital to giving enforcement authorities the tools they need to quickly locate infringing Internet sites and pursue actions against the offenders who commit the most damage and/or refuse to remove the infringing content. Public education about the dangers of online infringement must be emphasized as well. As global boundaries continue to lose much of their practical relevance because of Internet growth, so must the usual lines separating the roles of industry and government in policy, enforcement and education. Close coordination will be the key to success in this challenging new environment.

Finally, I mentioned the broad-based CACP coalition earlier and I would urge the Committee to give positive consideration to proposals the CACP has endorsed with respect to the creation of high-level leadership positions in the Department of Homeland Security, Customs and Border Patrol and other agencies, as well as the deployment of dedicated agents with adequate legal tools to protect our borders against counterfeiting and digital theft.

CONCLUSION

Effectively addressing piracy in all of its variants is a key economic and cultural objective for the United States. Congress, the Administration and the private sector must work together to achieve this goal. Trade pressure and capacity-building through effective training continue to be primary mechanisms for encouraging foreign nations to address inadequacies in their legal and enforcement frameworks, and I urge the Committee to ensure that the Administration has all the possible tools at its disposal to exert such pressure and to provide necessary training. To this end, it is critical that the Administration be funded in such a way as to permit them to use their powers to the maximum extent, and I urge the Congress to appropriate sufficient funds to protect America's most creative, vibrant and profitable industries.

We can and must prevail in these initiatives. Once again, I thank you for inviting me here today, and I look forward to your questions.

COMMUNICATION

**United States Senate Committee on Finance Hearing:
“International Enforcement of Intellectual Property Rights and American
Competitiveness”
July 15, 2008**

**Written Testimony of
Desiree G. Filippone
Vice President, International Government Affairs
Eli Lilly and Company**

Thank you, Chairman Baucus, Senator Grassley, and the entire Finance Committee for holding this important hearing today. Mr. Chairman, on behalf of Eli Lilly and Company, let me commend you and this Committee for championing the benefits of intellectual property (IP) protection for American industries and workers. Your thoughtful examination of the many issues related to global competitiveness deserves our deep appreciation. We thank you.

Demand for American ideas spans the globe, and while we must ensure that our nation’s innovators have the protections necessary for their work, we must also strive to be an active force in helping the world’s poorest countries.

One of the many IP issues the committee will look at today is the difficulty in providing access to medicines in the world’s poorest countries. It is an enormous challenge with complicated solutions. One of the efforts that Lilly has undertaken is dedicated to providing resources to disadvantaged populations to improve health and economic welfare, and today I would like to share with you our efforts to combat multidrug-resistant tuberculosis (MDR-TB) as an example of this work.

Diseases such as tuberculosis, or TB, if left untreated, inhibit one’s ability to earn an income, support and raise a family, and realize one’s dreams. Seventy-five percent of those infected with TB are between ages 15 and 54. Thus, TB affects the world’s workforce. There are almost nine million new cases of TB every year, of which 450,000 are multidrug-resistant. Multidrug-resistant TB, or MDR-TB, is as contagious as TB but its treatment is more complex, expensive, and longer in duration.

TB robs the world of an estimated \$12 billion in lost income every year. Poor, crowded living conditions also increase the risk of contagious infection. TB perpetuates a vicious circle. First, the disease exacerbates poverty, which in turn, increases the likelihood of contracting TB. The World Bank estimates that loss of productivity attributable to TB is four to seven percent of some countries’ entire GDPs. Given the direct link between TB and poverty, investing in effective prevention and treatment of TB produces immense social and economic returns.

In centuries past, TB was an equal opportunity pandemic. It infested the bodies of both the rich and poor. In 1920, the great Italian sculptor and painter, Amadeo Modigliani, died of TB at age 36. With no treatment available, this “consumption” was a death sentence. With the discovery treatments such as streptomycin in 1943 and isoniazide in the 1950s, life after TB was made possible, saving thousands, including South African leader Nelson Mandela.

Today, TB affects mainly the poor. However, with the rise of globalization and worldwide travel comes an increased risk of TB and MDR-TB’s spread. Recently, the world has seen a greater incidence of TB and MDR-TB throughout Western Europe and North America. As a matter of national security and social well being, we must all work to control TB’s reemergence.

On World TB Day 2006, Nobel Peace Prize Laureate Archbishop Desmond Tutu declared that Eli Lilly and Company’s MDR-TB Partnership was an “excellent example of coordinated action against the disease.” It was in 2003 that Lilly launched its pioneering partnership to fight the rapidly growing threat of MDR-TB worldwide by supporting the World Health Organization’s Green Light Committee in its plan to prevent and cure MDR-TB. Today the Lilly Partnership continues to support the WHO goal of treating some 50 million TB patients with TB and 1.6 million patients with MDR-TB by 2015.

The Lilly MDR-TB Partnership to fight the increasing global threat of multidrug-resistant tuberculosis is comprised of 18 public and private partners on five continents. These include:

1. Eli Lilly and Company
2. Aspen Pharmacare, South Africa
3. International Council of Nurses (ICN)
4. International Federation of Red Cross and Red Crescent Societies (IFRC)
5. International Hospital Federation (IHF)
6. Harvard Medical School and Partners in Health (PIH)
7. Hisun Pharmaceutical, China
8. Purdue University, USA
9. Shasun Chemicals and Drugs, India
10. SIA International, Russia
11. TB Alert
12. U.S. Centers for Disease Control and Prevention (CDC)
13. World Economic Forum (WEF)
14. World Health Organization (WHO)
15. World Medical Association (WMA)
16. TB Survival Project/Advocacy Partnership
17. Stop TB Partnership
18. RESULTS Education Fund

For five years, the alliance has supported a comprehensive, multi-pronged strategy to fight this disease. Working primarily in the four countries hardest hit by MDR-TB, China, India, Russia, and South Africa, the Partnership:

1. Promotes community support and patient advocacy, involving communities and business in MDR-TB prevention and treatment;
2. Implements MDR-TB health care treatment and training programs, and strengthens surveillance of drug resistance;
3. Transfers Lilly drug-manufacturing technology to local pharmaceutical companies and supplies medicines at preferential prices;
4. Conducts research for new drug discovery;
5. Works with policymakers to raise awareness and prevent the spread of MDR-TB.

With Partnership operations in some 50 countries, Lilly invested an additional \$65 million in 2007 to combat MDR-TB, bringing its total commitment to \$135 million for long-term, sustainable initiatives.

A cornerstone of the work by the Lilly MDR-TB partners is its success in influencing key MDR-TB policies around the world including introducing new treatment protocols and convincing the global health care community that treating MDR-TB is just as important as treating primary TB. More than 50 countries now have policies addressing this deadly pandemic. In the U.S., Lilly is working to support legislation introduced in the Senate and recently passed in the House of Representatives, which encourages the U.S. government to increase funding for global TB initiatives. We will continue to focus on this for the remainder of this Congress and beyond.

Mr. Chairman, thank you again for holding this important hearing, and providing a forum for discussing competitiveness and intellectual property – as well as the many challenges involved in helping the world's poorest countries. We believe that our MDR-TB partnership is one demonstrated solution to providing access to medicines, and we look forward to working together on this important issue in the future.

