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PROTECTING CONSUMERS BY PROTECTING INTELLECTUAL PROPERTY

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BEFORE THE

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PROTECTING CONSUMERS BY PROTECTING INTELLECTUAL PROPERTY

TUESDAY, JUNE 17, 2008

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, Pursuant to notice, at 10:06 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Cardin, Whitehouse, and Hatch.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. Good morning. I should note that we are going to be talking about intellectual property. It is nice to have Senator Hatch of Utah here with me. During a number of years, part of the time he was Chairman, part of the time I was Chairman, we put together bipartisan coalitions on intellectual property issues. It turned out to be a pretty effective partnership, so, Senator Hatch, I am delighted you are here.

I do not think there is dispute that our Nation is in economic and political turmoil. Gas prices have exceeded our worst fears, especially those of us who live in rural areas, as I do. They are continuing to rise. They highlight the entrenched power of overseas oil suppliers. Subprime mortgages have devastated many of our homeowners, and they have revealed serious flaws in our lending systems. Just reading the press again today, you discover more and more of this. Health insurance is still only a distant dream for millions of Americans in the wealthiest Nation on Earth. The costs in lives and dollars of the Iraq war mount higher by the day. We are deep into a Presidential election year, so the debate on these issues will only intensify as summer turns to fall and as politics becomes even more intense.

But today the Committee is going to address a significant economic issue confronting our Nation, which actually should have no partisan flavor whatsoever.

Intellectual property, and the creativity and innovation it represents, that is really the fuel in the engine of our economy. For the United States to maintain its position as the world's economic leader, we have to focus on protecting its industries' intellectual property. In a year like this, partisan legislation is impossible; even bipartisan legislation is unlikely. It is only truly non-partisan legislation that presents an opening for progress, and I want to give intellectual property enforcement legislation that kind of a chance.

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The piracy and counterfeiting of intellectual property has reached unprecedented levels in recent years. This theft costs the American economy at least $200 billion and results in the loss of 750,000 jobs per year. Just think of that. Stealing and counterfeiting of intellectual property costs the American economy at least $200 billion and loses 750,000 jobs per year. Think how much we could use those jobs. While this theft alone is unacceptable, it is not the only cost incurred by piracy and counterfeiting. You only have to look at reports of poisoned counterfeit toothpaste or dangerous counterfeit automobile parts that are entering U.S. markets. Think about that if you have had your brakes repaired. Were they counterfeit? Think of that when you suddenly need them in an emergency. These things are sold disproportionately to lower-income Americans. And when you see this and you see the fact that people's lives are at stake, you understand how important the enforcement of our IP laws is to protect the health and safety of the American people.

Now, we have representatives of pharmaceutical, automotive, and product safety industries here today who can attest to these dangers, but also to the vast resources they have to expend not to create new products but to protect American consumers from the dangers of these counterfeit products. I would like to see, and I suspect every one of them would like to be able to use that money for research and development of new products.

Our other witness today is from the Government Accountability Office. I have been troubled by reports from the GAO that have shown the ineffectiveness of the current enforcement strategies being employed by the Federal Government. The lack of coordination among the Federal agencies responsible for IP enforcement seems to be one of the biggest hurdles we face. I want to hear what other roadblocks are preventing effective IP enforcement.

I have worked for years, as has Senator Hatch, to strengthen our existing laws and give our law enforcement agents the necessary tools to combat infringement. Other Members of Congress have been active this session in offering legislation to strengthen the enforcement of IP laws. Even the Chinese Government, which allows some of the most rampant theft of intellectual property in the world, has suddenly begun to realize the value and the importance of IP enforcement now that their own intellectual property has been threatened, and they have begun to crack down on infringement of their Olympic copyrights. So it is not ever too late for the sinner to come to the church, but I thought I would never see the day.

Justice Kennedy reminded us in his opinion for the Supreme Court in the case of *Boumediene* v. *Bush* last week that "the only mention of the term 'right' in the Constitution, as ratified, is in its clause giving Congress the power to protect the rights of authors and inventors," referring, of course, to Article I, Section 8 of the Constitution. These rights in intellectual property have been fundamental to Americans since our founding and have never been more important than they are today. Enforcement and protection of these rights is too important to be addressed piecemeal. I think we have to examine enforcement efforts from the top down and the bottom up. I hope that those testifying today can help us on that.

Orrin, if you would just allow me to tell just a quick story, we have a manufacturer, actually one of the preeminent in the world, of snowboards, Burton Snowboards, in Vermont. I remember getting on an airplane years ago in Chicago with Jake Burton, and the two of us were squeezed back in the cheap seats, way in the back of this airplane.

And we are both fairly good size guys. And Jake said, "See that guy going up there into first class?" I said, "Yes."

He said, "You know, he represents a Chinese company that stole our design for ski boots that we spent hundreds of thousands of dollars to design for the safety and everything else. He can afford to fly first class because it does not cost him anything to steal the design and use it. We had to pay to develop it."

That has always stuck in my mind.

[The prepared statement of Senator Leahy appears as a submission for the record.]

Senator Hatch?

STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Senator HATCH. Well, thank you, Mr. Chairman, for the opportunity to say a few words this morning on the enforcement of intellectual property rights. I regret I have to go to another meeting in the Leader's office and will not be able to stay for much of the hearing. But we are paying strict attention to what you have to say.

The protection and the enforcement of intellectual property rights are crucial components that foster ingenuity and innovation, which in turn drive our economy. Without meaningful intellectual property rights protection, our artists, our innovators, our entrepreneurs, and workers will all suffer. But we should be mindful that abuse of IP rights is not just about downloaded music, pirated software, or fake designer handbags. All sectors of our economy are affected because of this, including pharmaceuticals, auto parts, and the quality and safety of our food, and so many other things.

Indeed, robust IP protection promotes the health and safety of every American person. Far too often, enforcement of these rights has not been as strong a priority as it should be. As a result, we have an environment in which the IP rights of others are treated casually or without any regard. This pervasive nonchalance stems not only from inadequate enforcement but also because of an inadequate education about the law.

For example, some believe that if it is on the Internet, it is free. Well, our Nation must take the lead in this endeavor, but everyone here already knows that this is a global problem, and the solution will require a commitment not only to beef up domestic enforcement, but it will also require a concentrated governmentwide effort to prevent intellectual property rights abuse.

Furthermore, I believe any meaningful solution will need to take an integrated approach with both domestic and international prongs which incorporate educational, judicial, and enforcement components to help this insidious attack on our intellectual property.

In order to accomplish this task, all stakeholders must cooperate and work in an integrated fashion with State, Federal, and international governments. In the Senate, we face the challenge of working with multiple committees that have jurisdiction over various aspects of the integrated approach I just outlined. Coordinating efforts may take extra time, but doing nothing seems to me to not be an option.

As technology advances and becomes more sophisticated, so does the enemy. As many of you already know, I am working on legislation in the Finance Committee that will provide our Government with the tools necessary to combat this very real and growing threat to our economy. And although I am not prepared to discuss the particulars of my legislative approach today, I hope upon introduction to work closely with this respective Committee to enact a comprehensive and well-balanced bill that will protect both the creators and the consumers of intellectual property.

This is an important hearing. These are important issues. We take a tremendous interest in them. I have particularly enjoyed working with Senator Leahy over the years and others on this Committee, but particularly Senator Leahy, on intellectual property issues. And we have consistently been able to get together in the best interests of our country, and for that I am very grateful to him.

And I am grateful to have all of you here today for the wisdom that you can provide to us in helping us to understand these issues better.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you very much.

Did you want to say anything, Senator Whitehouse, or we will just go right to the witnesses?

STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator WHITEHOUSE. I will have to go to the floor during the course of this hearing, so if I get up and leave, it is not because of anything anybody said. I am very interested in this hearing. I appreciate very much that the Chairman has held it. And when the time comes for questions, I would be particularly interested in the extent to which the cyber attack that the country is sustaining relates to efforts to steal intellectual property and take advantage of it in foreign countries.

Thank you, Chairman.

Chairman LEAHY. Thank you.

Shortly after the signing of the peace agreement between Egypt and Israel, Anwar Sadat, the President of Egypt, and Menachem Begin, the Prime Minister of Israel, came—that famous photo of the signing ceremony at the White House. They came up onto the Hill. We met separately with them in big receptions and a luncheon. When Prime Minister Begin was speaking, he started off with remarks that were a little bit critical of something that the Egyptians had done, and three Senators got up and walked out. He did not realize that the lights had gone off and that we had votes.

He looked a little bit nervous, and he said, "However, I must say this about President Sadat." And it was very favorable. Then it

goes on a while longer, and he says something else, and three more get up. The poor man is getting very, very nervous until Frank Church, who was then the Chairman of the Foreign Relations Committee, whispers to him what is going on. He said, "Oh. Of course, as Prime Minister, I am also a member of Knesset, the parliament, and I understand." Things went along a lot better. So we do explain to witnesses if we leave, it is not because of what you said.

Dr. Loren Yager is the Director of International Affairs and Trade at the U.S. Government Accountability Office. It is a position he has held since 2000. He has been at GAO since 1998. He previously directed the Office of the Chief Economist. Prior to his work with the GAO, Dr. Yager was an economic analyst with the Rand Corporation studying high-technology trade issues. He has completed several reports on Government agencies involved in intellectual property protection. He has offered congressional testimony on a variety of topics, including China import remedies and container security.

Dr. Yager, you are always welcome on Capitol Hill.

Please go ahead, sir.

STATEMENT OF LOREN YAGER, DIRECTOR, INTERNATIONAL AFFAIRS AND TRADE, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, D.C.

Mr. YAGER. Thank you very much, Mr. Chairman. Good morning, Mr. Chairman and members of the Committee. Thank you for the opportunity to discuss our work on U.S. efforts to protect and enforce intellectual property rights.

As you mentioned in your opening statement, the illegal importation and distribution of counterfeit and pirated goods poses a threat to the health and safety of U.S. citizens, as well as enormous costs to the U.S. economy.

However, the challenges involved in IP protection are also significant and include the technological advances that facilitate piracy as well as the need for effective coordination among a wide range of policy and law enforcement agencies.

In my summary today, I will address two topics: first, the need for greater leadership and permanence in our national IP enforcement structure and strategy; and, second, the need for key agencies to improve their data collection and analysis on issues related to IP enforcement.

My remarks are based on numerous assignments that GAO has conducted on intellectual property protection over the past 5 years and, most recently, a report issued to Senator Voinovich regarding U.S. agencies' enforcement efforts.

Let me first talk about the leadership issue. The current U.S. Government coordinating structure that has evolved for protecting and enforcing U.S. intellectual property rights lacks permanence, presenting challenges for effective and viable coordination over the long run. At present, we have a combination of leadership mechanisms.

The National Intellectual Property Law Enforcement Coordination Council, called NIPLECC, is responsible for coordinating IP protection and enforcement across multiple agencies. And the White House's Strategy for Targeting Organized Piracy, called

STOP, is the strategy that guides this council. NIPLECC has struggled to define its purpose and retains an image of inactivity within the private sector. It continues to have leadership problems despite enhancements made by Congress in December of 2004 to strengthen its role.

From the beginning of NIPLECC in 1999, Congress's goal has been to institutionalize law enforcement coordination. But our work suggests this goal has not yet been met. In contrast, STOP has a positive image but lacks permanence, and the momentum that it helped create could disappear after the current administration.

We have recommended that the IP coordinator and the STOP agencies clarify the relationship between the council and the White House strategy, but also recognize that some of the legislative proposals under consideration by the Congress call for more fundamental changes in this relationship.

Let me now briefly summarize the second issue, the potential for improvement in agencies' data collection and analysis on IP enforcement.

Federal IP enforcement functions include seizures, investigations, and prosecutions, and while IP enforcement is generally not the highest priority for agencies such as the Department of Justice, Department of Homeland Security, or Health and Human Services, addressing IP crimes with a public health and safety risk has become an important enforcement activity at each of those agencies.

Our report also provides some good news in that Federal IP enforcement actions generally increased during the years 2001 through 2006. Given the importance of this issue, there are some ways that the agencies can improve their data and analysis to enable Congress and others to better assess agency achievements. Let me give just a few examples.

Despite the fact that many agencies identified IP related to health and safety as a priority, we found that some agencies lacked the data to report or to analyze their efforts to address these types of crimes. We also found a few field offices were driving a huge share of some of the agencies' overall enforcement activity. But agencies had not always considered the implications of these patterns.

Most agencies had not established IP performance measures or targets to assess their achievements, making it more difficult for the Congress and for agency managers to make informed resource decisions and assess whether they are achieving their enforcement objectives. And, finally, the IPR Center was created with the mission to collect, analyze, and disseminate information about IPR enforcement. But the center has never achieved those goals.

We made a number of recommendations to the agencies regarding improvements, and these were similar to earlier recommendations made to the IP coordinator to improve accountability measures. We continue to work with the agencies in terms of their response to those recommendations.

Mr. Chairman, as you noted in your opening statement, a number of legislative proposals are before the Congress that would modify the Federal IP enforcement structure. As the Committee continues to consider this issue and these proposals, we would be

happy to provide additional information where we believe the proposals address the weaknesses that our work has identified.

Mr. Chairman, this concludes my prepared remarks, and I would be happy to answer any questions that you or other members of the Committee have.

[The prepared statement of Mr. Yager appears as a submission for the record.]

Chairman LEAHY. Thank you.

I would mention that Dr. Yager is very familiar with Capitol Hill. He ended within the time.

What I am going to do is have each witness testify, and then we will ask questions.

Brian Monks is the Vice President of Anti-Counterfeiting Operations at Underwriters Laboratories, something that is more than a full-time job, I am sure.

Underwriters, of course, is a nonprofit company that certifies public safety. In his role at UL, Mr. Monks works closely with the Bureau of Customs and Border Protection, the FBI, Interpol, as well as other international law enforcement agencies to identify and seize products bearing counterfeit UL marks. He has written numerous articles in industry journals, frequently addresses anti-counterfeiting conferences around the world. He is also a member of several anti-counterfeiting organizations, including the International Anti-Counterfeiting Coalition, where he is an executive board member.

Mr. Monks, thank you for coming, and please go ahead, sir.

STATEMENT OF BRIAN H. MONKS, VICE PRESIDENT, ANTI-COUNTERFEITING OPERATIONS, UNDERWRITERS LABORATORIES INC., MELVILLE, NEW YORK

Mr. MONKS. Chairman Leahy, distinguished members, thank you for this opportunity for Underwriters Laboratories to appear before you today. I am pleased to provide UL's perspective on our work to keep counterfeit products out of the marketplace.

Counterfeiting is a serious threat to our economy and to the safety of U.S. consumers. A variety of counterfeit products enter the stream of commerce every day, many posing unsuspectingly serious fire and electrical hazards that endanger the American public.

For 114 years, UL has built a reputation on the integrity of the UL mark and what it represents to consumers. The UL mission is the protection of human life and property from product risks and hazards. In 2007, an estimated 21 billion products entered the global marketplace carrying the UL mark. To put this in perspective, the average American consumer's home contains 120 products bearing the UL mark. Everything in this room today you touched electrically probably has a UL mark on it.

Like other brand leaders, the UL mark is being counterfeited—leaving consumers with a false sense of security about the safety of the products they purchase. To minimize this risk, UL maintains a zero tolerance policy, working aggressively with law enforcement to seize product and to prosecute counterfeiters.

There can be no doubt about the correlation between counterfeiting and product safety. Counterfeiters do not discriminate in their selection of products. They care about profit. In 2007 alone,

UL issued warnings about fire extinguishers, smoke alarms, extension cords, holiday lights, lamps, power strips, and surge protectors bearing counterfeit UL certification marks. Penetration of product and certification mark counterfeiting in electrical and fire protection categories increase the risk of fire, shock, and other hazards to American consumers, their homes, and their workplaces.

Common household extension cords can typically be purchased for under a dollar at discount stores nationwide. They are often targeted by counterfeiters. Producing them requires basically copper and plastic. To maximize their profit, counterfeiters use extra plastic and reduce the amount of copper. Reducing the amount of copper means that when the electrical current is applied—for example, plugging in a hair dryer—these products can overheat, melt, and catch fire.

In 2007, Customs and Border Protection made over 150 seizures of products bearing counterfeit UL marks. When examined, many of these products posed an unacceptable risk to the public.

Even more disturbing is the recent appearance of counterfeit marks on fire safety devices, such as smoke detectors, heat detectors, sprinkle heads, and fire extinguishers. Senator, these devices are designed to save your life in case of a fire.

Aggressive, proactive measures need to be taken to prevent the entrance of these products into the marketplace. They need to be stopped before a failure becomes another fatality statistic. We cannot overstate the importance of enforcement authorities and lawmakers working together with the private sector to combat these criminal activities. For over a decade, UL has worked closely with the Department of Justice, the Federal Bureau of Investigation, and other enforcement agencies to identify and seize products bearing counterfeit UL marks and to prosecute offenders to the fullest extent of the law.

UL's goal is to continue working with enforcement agencies to prevent these products from ever reaching the hands of the consumer. Ultimately, UL hopes that increased enforcement will deter counterfeiters. In 2006, the U.S. Attorney's Office of the Southern District of Florida announced that two defendants found guilty of trafficking in a range of products, including extension cords bearing counterfeit marks, were each sentenced to more than 7 years in Federal prison. The rights holders worked in partnership with Government to assist in successful prosecution, sending a message that counterfeiters that compromise the safety of American citizens will be pursued and punished.

As these examples show, some success has been achieved in combating the serious and growing threat of product counterfeiting. There is more to be done. Additional resources are necessary in order to continue this positive track record. We believe that additional staffing and resources for the DOJ and FBI that are dedicated solely to combating IP crimes would be a step in the right direction. This means things like dedicated FBI agents for existing or new Computer Hacking and Intellectual Property units; it means additional Assistant U.S. Attorneys dedicated to the prosecution of IP cases; and it means staffing available for the formation of ad hoc task forces that can be mobilized quickly to address short-term situations and threats to combat these dangers. These

ad hoc task forces have proven effective in New York, Newark, and recently Los Angeles, where the combined effort of Federal and local authorities were able to take down large-scale counterfeiting operations.

Let me leave you with a parting thought. Last Friday, Federal authorities seized $1.5 million in counterfeit circuit breakers. Circuit breakers are found in our home electrical panels and protect against electrical current overloading and fire. Had they not been seized, these breakers could have ended up in our homes. Senator, one shipping container holds 186,000 circuit breakers. To put that in perspective, that is the potential of 186,000 house fires.

Thank you very much.

[The prepared statement of Mr. Monks appears as a submission for the record.]

Chairman LEAHY. Thank you, Mr. Monks. We will get back to questions in a moment, but thank you for emphasizing two things: One, that counterfeiting is not just stealing money; it could cost you your life. You can go out and buy a product that you think is very reputable—my wife and I always look for the UL mark on electrical things we buy—but it could cost you your life. And, second, I like the emphasis you put on prosecution. As a former prosecutor myself, I think sometimes—I probably expect the finest motives of people, but sometimes the thought that the jail door may clang shut with them behind the door, that sometimes motivates them to be even more conscientious about following the law.

Mike Rose is the Vice President of Supply Chain Technology at Johnson & Johnson. He has been with them for over 30 years in a variety of positions within the company, including Chief Information Officer. Mr. Rose works with several industry associations on supply chain issues, including the Pharmaceutical Research and Manufacturers of America's Supply Chain Work Group. He is co-chair of the Health Care Distribution Management Association Industry Relations Council.

Mr. Rose, thank you very much for coming here. Please go ahead, sir.

STATEMENT OF MIKE ROSE, VICE PRESIDENT, SUPPLY CHAIN TECHNOLOGY, JOHNSON & JOHNSON, FOUNTAINVILLE, PENNSYLVANIA

Mr. ROSE. Thank you, Mr. Chairman.

Mr. Chairman, on behalf of the nearly 120,000 employees of the Johnson & Johnson family of companies, thank you for the opportunity to speak here today.

Violation of intellectual property through counterfeit health care products presents a significant risk to patients and consumers. Mr. Chairman, there are three points I would like to underscore this morning.

First, we believe that there should be one national standard for ensuring the integrity of the health care products supply chain.

Second, coordination among the various governmental agencies and industries involved in combating counterfeiting, as well as aggressive enforcement of existing laws, is essential.

Third, we must acknowledge that the lack of international enforcement of intellectual property laws allows counterfeiters to thrive.

According to the FDA, while the United States pharmaceutical supply chain is one of the safest in the world, counterfeiting of health care products is a growing concern. The World Health Organization estimates that 8 to 10 percent of pharmaceutical products outside the United States are counterfeit. In some countries, counterfeit products may represent 50 percent of medicines.

The Internet is fast becoming the marketplace of choice for counterfeiters where counterfeit pharmaceutical, consumer products, and medical devices can be purchased from unregulated Internet sites. Counterfeiters can easily sell their products via website and distribute them to unsuspecting U.S. consumers. This problem is so widespread that, according to the Pharmaceutical Security Institute, seizures of bogus prescription medicines jumped 24 percent to 1,513 incidents in 2007, and illicit versions of 403 different prescription drugs were confiscated in 99 countries.

Another avenue for counterfeiters is diversion, which refers to merchandise that is distributed into markets other than originally intended. Diverted products, so-called gray market products, frequently are past dated or expired, have been previously marked for destruction, have not been properly stored, or are counterfeit.

Counterfeiters show total disregard for the safety of consumers, patients, doctors, and nurses. They have no regard for intellectual property rights and take advantage of countries with gaps in intellectual property laws or where enforcement of IP laws is non-existent or lax.

Countries that do not enforce IP laws for products made for export provide counterfeiters a safe haven. The active ingredient can be manufactured in one country, exported to a second, where the product is packaged; exported to a third country, where it is labeled and placed in finished packaging; and exported for final sale.

Both health care manufacturers and Government regulators are taking action to combat counterfeiting and to protect consumers and patients. Many health care manufacturers have invested in measures to tighten the security of supply chains and products. Here are some examples where manufacturers are focusing their efforts: monitoring market activities and trading practices; collaborating with Customs and police to investigate suspected cases of counterfeiting or tampering; working with Government agencies to ensure trademark and IP laws are enforced and prosecuting infringements; applying overt and covert features to products and packaging to aid in product identification; and, last, investigating and piloting track and trace and pedigree systems to communicate the product's chain of custody. These systems are intended to add greater clarity into where products have been and where they are moving.

One area of special focus has been a product's pedigree, which documents the chain of custody of a specific product. More than 30 U.S. States have enacted legislation requiring pharmaceutical pedigrees. As a consequence, we have a patchwork quilt of pedigree laws and regulations that could defeat the purpose of improving supply chain security.

We believe legislative efforts should eliminate the complexity of multiple pedigree laws and implement a simple and potentially effective solution—the electronic pedigree, otherwise known as ePedigree.

Making the distributors produce ePedigrees would increase the effectiveness of law enforcement. The Federal Government can and should take the lead in establishing a single Federal standard for electronic pedigree.

We have submitted additional testimony and our recommendations to the Committee. Johnson & Johnson is committed to working with Congress, the FDA, and other Government agencies on counterfeit challenge and is ready to make our company experts available to assist with legislative and regulatory efforts.

Thank you for allowing Johnson & Johnson to share our perspective on this critical issue with you today. I am happy to answer your questions.

[The prepared statement of Mr. Rose appears as a submission for the record.]

Chairman LEAHY. We will go into those, but also, listening to your testimony makes me realize, too, that when you have a company like Johnson & Johnson that is a well-recognized name, like General Motors or something like that in cars. If somebody counterfeits your product and illness or death results from that, the billions of dollars that have been invested to buildup a basic product name is severely damaged. Is that not correct?

Mr. ROSE. That is correct.

Chairman LEAHY. I saw Mr. Monks shaking his head. The same would be with UL where an enormous amount of time has been spent to get into consumers' minds that this is a seal of approval, and there you are.

Jeffrey Thurnau is a patent attorney for the Denver-based Gates Corporation, where he has worked since 1999. Mr. Thurnau is responsible for assisting the administration of Gates' worldwide intellectual property portfolio, including preparation and prosecution of patent applications, trademark registrations, and licensing. Prior to joining Gates, Mr. Thurnau was a private attorney representing clients before the American Arbitration Association, the New York Stock Exchange in various State and Federal courts. He is a founding member of the Motor and Equipment Manufacturing Association Brand Protection Council.

Mr. Thurnau, please go ahead, sir, and thank you for being here.

STATEMENT OF JEFFREY THURNAU, PATENT COUNSEL, GATES CORPORATION, DENVER, COLORADO

Mr. THURNAU. Chairman Leahy, thanks very much, other distinguished members of the Judiciary Committee, thank you for this opportunity to testify on "Protecting Consumers by Protecting Intellectual Property." Gates is headquartered in Denver, Colorado. We have 5,000 employees at 25 facilities across America. The motor vehicle parts suppliers are the Nation's largest manufacturing sector, directly employing 783,100 people and contributing to 4.5 million jobs in private industry across the Nation.

Today I am going to focus my comments on the safety implications of counterfeit parts. I will begin with an overview of the coun-

terfeit challenges facing the auto parts industry, give you an idea of the issues facing Gates Corporation, and then offer some ideas, legislative and otherwise, that help move this important legislation forward.

Counterfeit parts and components for cars, trucks, buses, and commercial vehicles pose a critical problem to the American economy. Chairman Leahy mentioned the $2 million in annual losses to counterfeit sales, and in the auto parts industry, approximately 250,000 fewer jobs as a result of counterfeit parts in the marketplace.

Vehicle performance and safety can be severely impacted by counterfeit products such as brakes, brake pads, timing belts, automotive lighting, and tires. The use of counterfeit parts can result in sudden, catastrophic engine failure, brake failure, and other system malfunctions.

Trademark and brand infringement is the most immediate problem we face at Gates Corporation. That is because this represents the easiest method by which pirates can get their products sold in the marketplace.

Another issue we confront is trade dress infringement.

Trade dress relates to the unique or distinctive appearance of products or packaging. Often, the consumers are unable to distinguish the difference between the authentic goods and counterfeit goods and may mistakenly make a purchase of counterfeit products.

We have tested pirate timing belts and find they simply do not rise to industry standards. As I have said, failure of a timing belt can lead to catastrophic engine damage. This saddles the consumer with thousands of dollars in repairs, as well as presenting a significant safety risk when one considers where the failure may occur, for example, on a busy highway.

Let me give you some other examples. In March 2008, Taiwan customs contacted Gates with respect to a suspect shipment of counterfeit timing belts. Gates confirmed that they were counterfeit, and we are in the process of working with Taiwanese officials to move the case forward.

In November 2006, a Puerto Rican distributor was caught selling counterfeit timing belts. The supplier was located in China. The supplier had 600 timing belts in his possession and had been selling them on the Internet.

In October 2006, a Polish distributor was caught selling counterfeit timing belts. Warsaw authorities brought a criminal complaint against the distributor.

As you can see, a company like Gates faces a myriad of challenges to its intellectual property. I urge you to consider some of the following ideas to address the range of concerns I have expressed today on behalf of Gates and the Motor Equipment Manufacturers' Association.

First, better coordination among executive branch enforcement agencies. Current legislation provides three options worth looking at: Senate bill 522, with its OMB-centered Coordinating Committee; next, legislation recently passed in the House creates an IP czar at the Department of Justice; and last, but certainly not least, Mr. Chairman, your legislation, S. 2317, which provides for a spe-

cial unit at the FBI, as well as increased penalties for trafficking in counterfeit labels.

We also support increased enforcement resources at the Department of Homeland Security and the Department of Justice. This would be directed toward additional personnel, training, and technology for detecting counterfeit parts at U.S. ports.

Finally, we support increased coordination and cooperation among U.S. law enforcement agencies and the law enforcement agencies of like-minded countries so that the IP laws in those countries might be more vigorously enforced.

Mr. Chairman, thanks very much for the opportunity to testify today. I am glad to take any questions.

[The prepared statement of Mr. Thurnau appears as a submission for the record.]

Chairman LEAHY. Well, thank you, and I think you agree with me that prosecution alone is not the answer, but it is good to have some pretty tough teeth if you do catch people and prosecute them.

Mr. THURNAU. Yes.

Chairman LEAHY. Dr. Yager, let me ask you, the National Intellectual Property Law Enforcement Coordination Council, NIPLECC, as we have said, is an interagency group that is supposed to coordinate U.S. domestic and international IP enforcement activities. We had the former coordinator of NIPLECC, Chris Israel, before this Committee several times, and he was doing as well as he could. But NIPLECC itself is often criticized as being ineffective. In contrast, we have the Strategy Targeting Organized Piracy, or STOP. It seems to have done a little bit better in bringing in the Departments of Commerce, Justice, Homeland Security, State, Food and Drug, Office of the U.S. Trade Representative together.

Has STOP been more effective and why? And if it has been more effective, how can we make it even more effective than that?

Mr. YAGER. We believe that STOP actually did add quite some energy and some momentum to the efforts among agencies to work together to improve IP enforcement. I think there are a couple reasons for that. One, it was a very highly visible effort, not only inside the Government but in terms of outreach to the private sector. There was also some additional reporting and a little bit more in terms of accountability features, providing information to the Congress and other stakeholders as to what their goals were, and what was the purpose. They set some targets for performance. So I think there were a number of factors that made STOP more effective, including some fairly vigorous support from the White House. So it being an important effort within the administration gave it some additional prominence, and, frankly, it got the attention not just internally in the United States but also abroad. So there were some features about it that made it more effective than its predecessor.

On the other hand, one of the problems with a Presidential initiative is it is certainly possible that that initiative will go away with the new administration. So one of the points that I made in my statement and my written report was about the permanence of this particular entity, because after achieving some momentum along the lines of the things that I mentioned, as well as, frankly, some increased prosecutions at Justice. This problem obviously will

not be solved by the end of this administration, and there needs to be some discussion about how to make that group and that function more permanent to continue to make some progress on this difficult subject.

Chairman LEAHY. I wear another hat as Chairman of the Subcommittee that funds all of the State Department and its overseas operations. I have been pushing very hard to make sure we have people in our embassies who can work on these issues and train to.

I should probably ask Mr. Monks, and Mr. Rose and Mr. Thurnau, has the coordination worked well? It is one thing to have our agencies coordinate with each other. They are coordinating with the industry. Mr. Monks?

Mr. MONKS. I think the reach-out is mutual. You know, from private industry we reach out to the Department of Justice, to the Bureau, to ICE, whoever it may be, and educate, talk about the problem how we can work together to combine our resources to get effective enforcement, get effective prosecution. So it is a two-way street. From UL's vantage point, it has worked on many occasions where we have had some good prosecutions. We are certainly not catching all the crooks, but, you know, we are out there pushing the envelope.

So it has worked. There are some limitations. There is communication problems here and there. But overall we are quite happy with the outcome.

Chairman LEAHY. Mr. Rose?

Mr. ROSE. We have coordinated with various governmental agencies, and they are very important resources to us. In our industry, we work very closely with the FDA and also with the group in the FDA, the Office of Criminal Investigation. They are very important to us, and they have been great resources, as well as Homeland Security and ICE.

Coordination always is a difficult thing. As we look at counterfeiting, we have to also be cognizant that counterfeiting is occurring outside the U.S.; we need to have better coordination with regulatory agencies, and enforcement agencies overseas.

Chairman LEAHY. Mr. Thurnau?

Mr. THURNAU. Thank you. Let me take that segue in terms of international efforts. From the Gates Corporation's point of view, our primary issues are offshore, and we have had some success in dealing with U.S. agencies, but at the moment, we also are trying to beef up our contacts with other governments, other law enforcement agencies in those governments, so that they are familiar with us and familiar with the products and the automotive industry products. So to the extent that U.S. agencies can assist in that coordination effort between U.S. and other governments, it would be appreciated.

Chairman LEAHY. Well, thank you. And, you know, I would hope that each one of you would feel free, after you think further on this, to write to me if you have ideas, concrete things that you feel that could be done, and write to both myself and Senator Hatch, who is interested in this. This really is not a partisan issue. It is one that we all have a stake in. I have a lot of small companies but very big companies in my own State of Vermont that have inter-

national work, many in the electronic areas, other types of areas, and one that does circuit breakers that you have certified, Mr. Monks, your company has. And they are constantly being faced with counterfeit products labeled as theirs, and they do not begin to match the quality of theirs.

Mr. Rose, we just touched on this earlier, but just give us some idea of what you have to do in your company, a brand that we all recognize, what you have to do just to protect your brand name that people are counterfeiting and thinking they are buying a Johnson & Johnson brand. I am sure that what you would say is probably could be said by just about every large corporation in this country.

Mr. ROSE. I will speak on behalf of the health care industry. I am sure Mr. Thurnau could comment on the automotive industry as well.

What we are seeing is a huge investment of resources and time. If you go back 30 years ago, this was not an issue on anyone's agenda. We were developing products and marketing products. Now we have added another dimension to our supply chain activities where we have to protect our products. So we invest in various anti-counterfeiting measures and features for our products, overt and covert markers, color-shifting inks and holograms. We have invested in time with our trading partners to reassess our agreements, our trade agreements that we have with them. We are monitoring the marketplace as well.

These activities are taking a lot of resources, corporate resources, that we now have to invest in just to protect products. We manufacture genuine products, and as you rightfully mentioned, the Johnson & Johnson name is a very important name to protect. Now we have to invest to protect that name even more than we ever have in the past.

Chairman LEAHY. It would be more fun to be spending that money on developing new products, I am sure.

Mr. ROSE. We would all benefit from spending money on new products. Many of us would benefit from having new medical products.

Chairman LEAHY. I am going to yield to Senator Cardin in just one moment, but, Mr. Thurnau, when I walked in, I noticed you had a belt over there, and I am sitting here intrigued. Would you tell me what that is?

Mr. THURNAU. Absolutely. Thank you. I brought in an authentic belt and a counterfeit belt and some authentic and counterfeit packaging as well. And the point is that counterfeiters to a certain extent have to meet quality standards, as odd as that sounds, because even though it is a point-of-sale issue for the purchase of counterfeit products, they still have to get past that initial purchase. So often it is very difficult to distinguish between the authentic goods and the counterfeit goods. I am glad to offer these up for inspection by the Committee.

Chairman LEAHY. Thank you.

Senator Cardin?

Senator CARDIN. Well, Mr. Chairman, thank you very much for holding this hearing, and I thank our witnesses for their testimony. The stealing of intellectual property is a very serious problem. It

is not only an economic loss. It is a fairness issue. It is a safety issue. And I think you all have pointed that out in your testimony. And whether we are dealing with pirated goods or we are dealing with counterfeit products, it is a huge problem.

And there is an attitude issue. I think people in this country do not realize that when they take a pirated product, it is stealing; or that when they use software that they get from a friend without a license, it is stealing. When they look for a product that might be counterfeit and are not really too concerned about it, it is stealing. And we need to do a much better job on enforcement.

In the last Congress, I served as the ranking Democrat on the Trade Subcommittee of the House Ways and Means Committee. I spent a lot of time dealing with intellectual property issues in our trade agreements. So I just really want to ask the panel a question. This hearing is primarily focused as to how we can strengthen our internal enforcement of our intellectual property rights, how we can help enforce the laws of this country, strengthen the laws.

One could say, Are our laws adequate? That is, is it clear what is legal and what is not legal? Second, do we have the right enforcement? And we have been talking here and the Chairman has been very active as to the coordination of so many agencies that are involved here, whether there should not be a better way to coordinate that, either through a central person or through a better focus within an agency. And the third is whether we should be looking at our trade laws in a different light.

I remember discovering in regards to counterfeit products that other countries that we trade with actually finance the manufacturing operations of counterfeit products. They actually assist in getting U.S. product to their country, which they analyze, then they set up manufacturing plants that produce that product in a counterfeit way for their own economic advantages, which is clearly something that should never be tolerated by the United States for a trading partner or any other country. So the question really is: Do we need to take a new look at our multinational trade agreements or our bilateral trade agreements or our U.S. attitude as to which countries we will allow access to our country if they are not enforcing basic intellectual property protections for U.S. manufacturers and producers?

So, yes, we have got to take care of our own domestic laws. We have to take care of enforcement here. We have got to take care of our trade laws. And if you could just help me a little bit as to where we should place our priorities in regards to being the most effective in preventing the stealing of intellectual property with American companies and individuals.

Mr. YAGER. If I could answer that, Senator Cardin, I think certainly we will not be successful if our efforts end at the U.S. borders in terms of trying to protect the U.S. from the entry of these goods.

There is a procedure, there is a special 301 process, which includes a number of the different agencies, and the focus of the special 301 process is for Government to get together with different industry representatives and foreign governments to talk about the ways that their legislation abroad can be improved. And there also

has been some discussion about enforcement of those laws within the special 301 process.

So there is an active process within the Federal Government that has been relatively successful—

Senator CARDIN. The United States has been challenged internationally on its enforcement, and in the latest round, there was a fear that we might have actually weakened some of our enforcement provisions. We did not get to that point, but it does not seem like we are winning in the international arena.

Mr. YAGER. There certainly have been some situations where the special 301 tool has been used against countries like Russia, Ukraine, and others to exert pressure. In some cases, there has been stronger legislation written in those countries. I have to say, though, the real difficulty with working with foreign countries is to try to convince them to put resources into this effort because, obviously, stopping the production of pirated goods abroad is a very resource-intensive effort, as it is here. And one of the things that we noticed when we did some travel is if there are groups within the law enforcement agencies abroad that are serious about seizing counterfeit goods, they have a storage problem very quickly. There is just so much counterfeit merchandise in many of these other cities that if the agencies, whether they are police or other, get serious about this, in a matter of days of seizures they have trucks full of counterfeit goods that they somehow have to try to destroy while keeping enough evidence to prosecute.

So it is an enormous effort where I believe the U.S. Government has been somewhat successful in helping them strengthen the laws, but the enforcement is still a major challenge.

Senator CARDIN. I would point out, if a country wants a trade agreement with the United States or, as we negotiate the multinational trade agreements, it should be, I think, high on our agenda to deal with how those nations are enforcing protection against taking of intellectual property. What resources are they putting behind enforcing the laws they have on the books to protect in this area? And certainly—and this is very true in the auto parts area. They certainly should not be helping to finance companies in their own country that are making counterfeit product. And that has been true of some of our trading partners. You at least want them to stop encouraging it, and certainly we would like them to enforce by confiscating counterfeit products and making sure they do not get into commerce.

Mr. THURNAU. Yes, Senator Cardin, exactly. We agree.

And enforcement in those countries presents a problem, and it is not entirely clear in all instances that enforcement has taken place, even when there has been a successful seizure or shutting down of a pirate operation. It is not uncommon that they simply reopen someplace down the road and put a different label on, and they are off and running again.

So there does seem occasionally to be lack of interest on the part of these governments to follow through with the process, either destruction of the physical plant that was doing the counterfeit operation, incarceration of the individuals who were involved, and it is a serious problem. We agree.

Senator CARDIN. I thank the Chairman. I guess my point is, Mr. Chairman, you are absolutely right to put attention in this hearing on the jurisdiction of our Committee to enforcement of our IP laws. We need to do a much better job here in this country. But we also need our trade representatives to put a higher priority on IP protections on the trade agenda so that you do not have to fight as hard with other countries as you do only to find when you win what you think is a battle, they just move down the street and open up another operation and you really have not gained anything other than costing a lot of energy and time and resources of your company.

Thank you, Mr. Chairman.

Chairman LEAHY. Thank you very much, Senator Cardin.

We talked about the cost of the theft of intellectual property. Mr. Rose, do you know offhand how much your company spends to protect your intellectual property a year?

Mr. ROSE. Mr. Chairman, I do not know the exact number that we spend to protect our intellectual property. I think it is hard to estimate because we integrate it into so many parts now of our company, and we do not look at it as an isolated cost. We can tell you some numbers. We have seen from the World Health Organization, we understand the economic impact is about $40 billion just to the pharmaceutical industry alone. And as you know, Johnson & Johnson is a medical device company, as well as a pharmaceutical company, as well as a consumer products company. So that is just one estimate for the whole pharmaceutical industry globally, $40 billion, what it costs us and what the economic impact would be. What it means specifically for our company, we do not have a good estimate for that.

Chairman LEAHY. Mr. Monks, do you have any idea?

Mr. MONKS. It is in the several millions of dollars. This is my full-time job. This job did not exist with this function UL 15 years ago, so it is relatively new. And it is global in its reach. And I would just say if we put in, you know, another thousand people into the job, it still would not be enough. It is growing at an epidemic level. It is in the millions. And it has to be spent because like Johnson & Johnson and everyone else that is in this room, the integrity of the UL mark cannot be tarnished, that if people plug something in, they expect it to be safe. And so we have to put this asset in place and protect the mark.

Chairman LEAHY. Mr. Thurnau, and I realize that I am jumping around here a little bit, but we have heard about organized criminal syndicates, especially in Eastern Europe and China, counterfeiting American goods. Has that been your experience? Are they a major force in all of this?

Mr. THURNAU. It has. We in the past, had instances in Russia, for example, where the counterfeiting operation, as far as we understand, was based in organized crime. And it presented problems for the investigators and for the individuals who are dealing with the counterfeiters. So we have run across that, yes.

Chairman LEAHY. Should we be looking at changes in our RICO statutes or anything in our criminal laws that we should change? Or is it simply a case of enforcement and trying to grab people?

Mr. THURNAU. I think in this case, sir, it is a matter of enforcement, resources being allocated in terms of Federal agents and prosecutors to, as you say, put people behind bars.

Chairman LEAHY. I realize this is kind of a broad-based question, but have you found in some of these countries that there is at least implicit government support, if not direct?

Mr. THURNAU. Yes, but not at the central government levels. It is usually at the provincial or city levels where the folks who we are working with may have an interest in the operation itself, so they have got the bias in favor of seeing that it continued to operate. That has happened, but as I said, not at the central government level, primarily provincial and city.

Chairman LEAHY. You know, I have been following this. I have had so many briefings, both public briefings and closed-door briefings of this. It is hard to think of any area of crime, and international crime as well as internal crime, that has grown so fast in this whole area.

Mr. Monks, we try to figure out ways to stop the counterfeiting of seals, whether it is the UL seal or any other seal. Should we be doing more in that? Do we need more laws in place? I am happy to push for laws, but I am also trying, as I—again, we are not trying to bring everything back to one's own experience as a prosecutor. I recall telling the Vermont Legislature once, when we had a rash of armed robberies around the State, I said, "We need some help to get that." They said, "Well, we will double the penalty." I said, "People do not think they are going to get caught. Doubling the penalty does not do anything. You need people to go out there and catch them."

If you wanted to leave me with any last thought, what would it be?

Mr. MONKS. I think the clang of the jail door is really a deterrent. More police tuned into, trained on IP crime. It is quite possible that police officers walk into a warehouse and seize drugs and weapons, and then there is a bank of DVR players, and they think the guy is into hi-fi. But, really, he is counterfeiting movies and making money.

It is the prosecution of these individuals. You need to create the laws that makes a deterrent to steal, because counterfeiting right now is all about stealing, and if I am going to steal and bring a shipment in of a million dollars and I get caught and the fine is $25,000, I will play that game every day with you. It is a win-win for the counterfeiter.

So it is not only prosecution, putting the assets on the ground, the police officers, the law enforcement, the customs agents, and taking it to them.

Chairman LEAHY. I think we have to do a better job of letting people know that people die from some of these things, not just buying a counterfeit article of clothing. And I am not suggesting in any way to condone that if somebody has done their own design and done the work. But if your seat belt does not meet the standards, if your medicine does not meet the standards, if your brake pad does not meet the standards, you can die.

One of the things that I am glad to see—and I have talked about this not being a partisan issue. It is also one where labor and busi-

ness have joined together. I know organized labor has joined industry in promoting stronger intellectual property protection. We have all got a stake in this. You have got the stake of your reputations. We have the stake of our lives. We also have the stake of jobs. And we all know that in today's world, you are going to have international competition anyway. And that is significant. It is a fact of life. But I would kind of like to have fair competition. Most of the corporations I have known in this country can keep the rules the same for everybody. They can compete. You can make tough competition, but they can compete. It is when somebody does not have to follow the rules where you have a difficult time.

Well, gentlemen, I appreciate your being here. You will get a copy of the transcript. If you want to add to it, please feel free. But also know that almost every member of the Committee has about three different meetings going on today, but we are going to be talking about this in the Committee. Feel free to add anything you want to.

We will stand in recess. Thank you.

[Whereupon, at 11:07 a.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

the standard in safety

Underwriters Laboratories

July 8, 2008

Senator Patrick Leahy
Chairman, Committee on the Judiciary
United States Senate
224 Senate Dirksen Office Building
Washington, DC 20510

Chairman Leahy:

I would like to thank you and the Committee for the opportunity to testify before you on intellectual property issues and "Protecting Consumers by Protecting Intellectual Property."

Enclosed please find responses on behalf of Underwriters Laboratories Inc. (UL) to the additional questions submitted by committee members for the official Committee record.

I applaud the Committee's attention to this important matter and encourage continued action toward fighting IP threats. Please do not hesitate to contact me, or feel free to reach our to our Washington, DC staff, should you require any additional materials or information.

Sincerely,

Brian Monks
Vice President, Anti-Counterfeiting Operations

Enclosure

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T.: 202.296.7840 / F.: 202.872.1576 / W.: ul.com

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Underwriters Laboratories

Responses from Brian Monks, Vice President of Anti-Counterfeiting Operations
Underwriters Laboratories Inc.

Following the Senate Judiciary Committee Hearing
"Protecting Consumers by Protecting Intellectual Property"

1. *To what extent do you think the protection of intellectual property is hampered by the scope of federal agencies' prosecutorial powers, as opposed to limited personnel and resources focused on enforcement?*

We at Underwriters Laboratories believe that the biggest obstacle to prosecutions of intellectual property violators is the lack of dedicated personnel on these issues and the limited resources available to pursue action against the criminals involved in these grievous crimes. Currently the prosecutorial powers and laws exist to pursue action, and while these laws and authorities can always be stronger and include stiffer penalties for violations, the true barrier to pursuing cases is the limited agents and attorneys available to engage. An essential first step would be to make available resources in the agencies with jurisdiction to create dedicated teams to pursue more cases under the currently available authorities.

2. *Who are the offenders for whom federal involvement is most needed? Are they primarily criminals engaged in large-scale operations, particularly ones that are international in scope or are involved with organized crime syndicates?*

Intellectual property (IP) crimes are economic crimes for the most part – those individuals involved risk little penalty, but stand to gain deep economic benefits. The nature of the crime creates an environment where a specific "type" of offender cannot be singled out as the culprit as many participants see access or advantage and engage themselves at various stages of the manufacturing and distribution chains.

However, we do know from experience that this is a problem global in nature. No country is exempt from IP crimes and the manufacturing of counterfeit goods often occurs in foreign markets before being shipped elsewhere for sale - including to countries like the US. We also know that the crimes are often organized and are large scale operations as individuals involved in these crimes often are involved in IP crimes across are range of product categories and across global jurisdictions.

We at Underwriters Laboratories believe it is important that federal authorities should continue to prioritize those cases where the counterfeited products put at risk the life and safety of the consumer – including counterfeit UL Marks, pharmaceutical products, and other life safety goods.

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July 16, 2008

The Honorable Patrick J. Leahy
Chairman, Committee on the Judiciary
U.S. Senate
Washington, DC 20510-6275

Dear Chairman Leahy,

This is in response to your questions following the Senate Judiciary Committee Hearing "Protecting Consumers by Protecting Intellectual Property". Please feel free to contact me with any more questions on this issue.

Question 1: To what extent do you think the protection of intellectual property is hampered by the scope of federal agencies' prosecutorial powers, as opposed to limited personnel and resources focused on enforcement?

Prosecutorial powers for Intellectual Property (IP) enforcement primarily rest with the Department of Justice. Although the Department of Justice sets the guidelines for all U.S. Attorney's offices, there are 93 U.S. Attorneys who establish their own guidelines that direct the level of support for IP matters by Federal agencies. IP matters do not generally appear to be as significant a priority as violent crimes, terrorism, or drug investigations except when a death occurs or there is a real safety risk to the public. Prosecutorial efforts are often hampered by the differing priorities of investigative agencies that frequently result in reduced investigative resources to support prosecution of IP matters. A vigorous enforcement effort cannot succeed without dedicated resources from investigative agencies that compliment prosecutorial resources. Strengthened enforcement is not about enhancement of resources, but about utilization of dedicated resources to properly address IP matters.

It has been our experience that counterfeit pharmaceutical and medical device products are generally manufactured overseas by unscrupulous businessmen who operate freely around the world and occasionally import these counterfeit products into the United States disguised as authentic products. Often they operate from jurisdictions that are lax in enforcement and prosecutorial efforts, which make the risk of being caught an acceptable cost of doing business. Vigorous enforcement and prosecutorial efforts need strong

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criminal statutes and the ability to extradite major offenders as key components of a strong IP plan that is designed to protect the public.

In many cases the protection of IP and subsequent prosecutions are hampered by an inability of investigative agencies to obtain information on the spot during an investigation. Requiring the timely production of documentation, like an e-pedigree, or greater use of administrative subpoenas at the time of a search or inquiry would immediately allow federal agencies to develop a strong investigative plan that would greatly protect the public and result in more prosecutions. In this day of rapid communications, inexpensive technology and global movement of products the ability of investigative agencies to quickly follow an investigative trail is critical to the protection of the public.

Greater transparency for imported and exported shipments involving the contents of a container would allow investigators both private and public to obtain significant information about the destination of products that have been diverted or identified as being counterfeit. Greater transparency over imports and exports would significantly expand the utilization of private investigative resources to combat IPR issues.

Requiring internet sellers of pharmaceutical products and medical device products to be certified by an independent government agency with regulatory and enforcement powers would provide the public with a greater sense of confidence that on line pharmacies and auction sites are selling only legitimate products to U.S. patients. The ability to regularly audit both the issuance of prescriptions and the sale of online pharmaceutical products and medical devices by a federal agency would provide greater protection to the consumer. Auditing of purchasing records combined with a review of authentic e-pedigrees would enhance the ability to successfully prosecute sellers of unauthorized or counterfeit drugs and medical devices via the Internet. Consumers who use the internet for medical purchases have no ability to determine the authenticity of a product or the origin of the product, which puts the consumer at risk without some regulatory oversight.

Question 2: Who are the offenders for whom federal involvement is most needed? Are they primarily criminals engaged in large-scale operations, particularly ones that are international in scope or are involved with organized crime syndicates?

Federal involvement is needed when organized domestic and international criminal organizations are involved in IP matters. However counterfeiting operations are not always confined to organized crime syndicates or criminals involved in large-scale operations. Johnson & Johnson's experiences with counterfeiting operations have often indicated that there is a loose network of individuals or very small businesses that engage in both legitimate and

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illegitimate transactions. These counterfeiters engage in counterfeiting because significant financial rewards are possible with a low risk of apprehension and conviction. Today's counterfeiters utilize global contacts, proprietary information, inexpensive and readily available technology and lax government involvement to pursue significant profits with little expenditures. Federal involvement is needed in IP investigations at the time of an initial report since it is difficult to identify the major offenders at the start of an investigation. A recent report from the Pharmaceutical Security Institute (PSI) indicated that stolen, counterfeit or diverted products have been found in 118 countries, which we believe indicates that involvement in counterfeiting is not solely limited to criminal syndicates.

Task forces that incorporate the skills and legal jurisdictions of local, state, federal and international law enforcement are critical to keep consumers safe from counterfeit products. The Federal Government should be a leader in coordinating the sharing of information among law enforcement and the private sector to significantly increase enforcement efforts in IP matters and assist in the development of credible and actionable intelligence. It is noteworthy that the National Intellectual Property Rights Coordination Center in Arlington, Virginia opened last week and is dedicated to the targeting of IPR crimes. The use of this center should enhance the efforts of law enforcement and private industry in better protecting the American consumer.

Prosecutorial and regulatory efforts from the Federal Government are key to protecting the supply chain and the ability to rapidly respond to reported incidents of counterfeiting or theft. An increase in criminal penalties for IP matters and an ability to swiftly extradite offenders for U.S. prosecution would demonstrate the commitment of the U.S. Government to protect IP rights both here at home and abroad.

Federal involvement is critically needed in instances where both the health and safety of consumers and multiple locations are involved. The ability to respond rapidly to multiple sites based on an initial report of an illness or injury is critical to insuring the safety of the public.

Thanks again for the opportunity to serve the committee.

Sincerely,

Mike Rose
Vice President

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Tomkins

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July 8, 2008

Justin Pentenrieder
Hearing Clerk
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Re: U.S. Senate Committee on the Judiciary Hearing, June 17, 2008
"Protecting Consumers by Protecting Intellectual Property"
Written Questions

Dear Justin:

Thank you for giving us the chance to respond to Written Questions from the Judiciary Committee members. I appreciate the opportunity to provide additional information to the Committee on this important topic.

Please let me know if you have any questions or need further information.

Sincerely,

Jeffrey Thurnau

Attachment

Questions of Chairman Patrick Leahy
Following the Senate Judiciary Committee Hearing
"Protecting Consumers by Protecting Intellectual Property"

Jeffrey Thurnau
Patent Counsel at Gates Corporation

1. To what extent do you think the protection of intellectual property is hampered by the scope of federal agencies' prosecutorial powers, as opposed to limited personnel and resources focused on enforcement?

We believe that realistic deterrence can only be accomplished with strong leadership and participation at the federal level. Successful deterrence must be based upon the expectation of being detected and prosecuted. The absence or diminution of this risk simply invites the pirates to keep operating and to accept getting caught as simply a cost of doing business.

We believe that protection of intellectual property may be enhanced by expanding the scope of federal agencies prosecutorial powers to include criminal prosecution of persons who knowingly infringe valid US patents. This will have the immediate effect of significantly increasing the personal risk to counterfeiters, a feature which is currently missing from US laws. It will also allow for seizure of equipment in the US that is used to produce the goods that infringe US patents.

However, in our view the primary issue is not the sufficiency of US laws, but instead is enforcement of existing laws. Within each agency it is our understanding that enforcement is a function of resources and priorities. Lack of resources apparently forces each agency, for example DOJ, ICE and CBP, to "raise the bar" when deciding which IP cases they will investigate and prosecute. The decision can be based upon the level of provable damages or perceived level of threat to the health and welfare of the American people. If the case is not of a sufficient financial size or risk, it will not be taken up.

By contrast, many civil actions brought by manufacturers in the US may not be driven by significant actual damages, but instead will seek injunctive relief to prevent

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importation of counterfeit goods and seizure of existing inventory.[1] Our primary goal is to protect the integrity of our brand and our reputation in the market for producing safe and reliable products over the long term.

The resource problem also directly affects the training available for existing enforcement personnel as well. Intellectual property violations can present complex and unfamiliar issues which may lead to a case being passed over which would otherwise merit prosecution.

Another significant problem that we face is the inability of federal agencies to fully coordinate their activities. For example, ICE and CBP apparently make every effort to coordinate their activities, but absent a central authority enforcement is subjected to multiple standards of review. This is inefficient, and diminishes confidence in the process on the part of the legitimate manufacturer. The supplier may be faced with the dilemma of shopping its case among various agencies in the hope of making the right choice. A central IP coordinating authority with responsibility for investigation and prosecution will help to minimize or eliminate this problem. It would be encouraging to see agencies working together, believing in the merits of a case and working aggressively to solve it.

While we don't have strong feelings about where the IP enforcement coordinator is housed, we are very much in favor of the concept. We could support an IP coordinator at the Department of Justice, or at another agency. Another option would be to house the official at the White House at the Office of Management and Budget, or elsewhere.

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[1] An example of pirates' lack of respect for US enforcement can be found at various automotive and industrial trade shows across the US and other countries. The pirates offer counterfeit goods to buyers along side legitimate manufacturers at the shows. Pirates have been known to solicit business at these shows offering to copy any product or trademark. The counterfeit products or trademarks are usually manufactured offshore. The Motor and Equipment Manufacturers Association, which sponsors the annual Automotive Aftermarket Products Expo, has experienced some success in curbing pirating by requiring all presenters to sign a contract that prohibits intellectual property rights infringement and counterfeit goods at the show and states that counterfeiters will be sanctioned including possible expulsion from the show. The government may wish to consider a similar approach for trade shows it supports. However, this is not a fully satisfactory resolution. The pirates may simply reappear at the next trade show. The fact that pirates will take this risk demonstrates they have little fear of detection or prosecution.

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The automotive and industrial parts supply industry appreciates that prosecution of criminal behavior such as drug trafficking and terrorism is necessary and important. It demands a significant commitment in terms of federal personnel and other resources. We understand that counterfeiters that are involved in drug trafficking and terrorism often use the proceeds of IP piracy to fund their heinous crimes. Further, enhanced IP enforcement is critical to encourage and support technological innovation that provides the engine of U.S. and global economic growth. Strong intellectual property is a cornerstone of U.S. economic competitiveness and provides high skill jobs for millions of Americans.

2. Who are the offenders for whom federal involvement is most needed? Are they primarily criminals engaged in large-scale operations, particularly ones that are international in scope or are involved with organized crime syndicates?

It is our perception and experience in the automotive and industrial parts supply industry that the majority of the offenders in the US are individual operators without a large well organized structure, either locally or internationally. Most offenders appear to be small companies or individuals. Most counterfeit automotive and industrial parts are manufactured offshore and then imported to the US. Pirate suppliers generally import in small quantities, hundreds or thousands of parts, while mislabeling the manifests to further avoid detection. The pirate may ship the goods in one container and the counterfeit labels in another. The counterfeit labels are applied to the goods at the destination.

The majority of pirate goods for the US automotive aftermarket industry originate offshore, primarily from China, although other sources include Russia and India. Our experience in China shows the counterfeiters there are mainly small companies or individual operators who can more easily escape detection, and once caught may be allowed to reopen shortly thereafter in a new location.

This is where enhanced coordination of federal agencies with agencies in other like minded countries will be beneficial. Pirates must make an investment in manufacturing equipment, regardless of where they are located. Some of this equipment can be very substantial and not easily moved, including molding casting and machining equipment. Pirates will locate their facilities in those countries where they believe they can escape detection, prosecution or seizure of their manufacturing equipment. Cooperation between US and foreign agencies will serve to reduce the number of friendly venues for pirates.

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SUBMISSIONS FOR THE RECORD

Statement
United States Senate Committee on the Judiciary
Protecting Consumers by Protecting Intellectual Property
June 17, 2008

The Honorable Patrick Leahy
United States Senator , Vermont

Statement of Senator Patrick Leahy,
Chairman, Senate Judiciary Committee
Hearing on "Protecting Consumers by Protecting Intellectual Property"
June 17, 2008

There is no dispute that our Nation is in economic and political turmoil. Gas prices have exceeded our worst fears – and are continuing to rise – and they highlight the entrenched power of overseas oil suppliers. Subprime mortgages have devastated many homeowners, and they have revealed serious flaws in our lending systems. Health insurance is still only a distant dream for millions of Americans. The costs in lives and dollars of the Iraq war mount higher by the day. We are deep into a Presidential election year, so the debate on these issues will only intensify as summer turns to fall, and as partisan politics becomes ever more intense.

Today the Committee addresses a significant economic issue confronting our Nation. It should have no partisan flavor whatsoever. Intellectual property, and the creativity and innovation it represents, are the fuel in the engine of our economy. For the United States to maintain its position as the world's economic leader, we must focus on protecting its industries' intellectual property. In a year like this, partisan legislation is impossible; even bipartisan legislation is unlikely. It is only truly non-partisan legislation that presents an opening for progress. I will give intellectual property enforcement legislation that chance.

The piracy and counterfeiting of intellectual property has reached unprecedented levels in recent years. This theft costs the American economy at least $200 billion and results in the loss of 750,000 jobs per year. While this theft alone is unacceptable, it is not the only cost incurred by piracy and counterfeiting. One need only look at reports of poisoned counterfeit toothpaste or dangerous counterfeit automobile parts that are entering U.S. markets -- and which are sold disproportionately to lower income Americans -- to see how important the enforcement of IP laws is to protecting the health and safety of the American people. We have representatives of pharmaceutical, automotive, and product safety industries here today who can attest to these dangers, and to the vast resources they must expend to protect American consumers from the dangers of these counterfeits, resources that they could put to much better use in research and development of new products.

Our other witness today is from the Government Accountability Office. I have been troubled by reports from the GAO that have shown the ineffectiveness of the current enforcement strategies being employed by the Federal Government. The lack of coordination among the Federal agencies responsible for IP enforcement seems to be one of the biggest hurdles we face; I am interested in hearing what other roadblocks are preventing effective IP enforcement and what suggestions the GAO has for improvements to the current system.

I have worked for years both to strengthen our existing laws and to give our law enforcement agents the necessary tools to combat infringement. Other members of Congress have been active this session in offering legislation to strengthen the enforcement of IP laws. Even the Chinese government, which allows some of the most rampant theft of intellectual property in the world, has realized the value and

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importance of IP enforcement now that their own IP has been threatened, and they have begun to crack down on infringement of their Olympic copyrights.

Justice Kennedy reminded us in his opinion for the Supreme Court in the case of Boumediene v. Bush last week that "the only mention of the term 'right' in the Constitution, as ratified, is in its clause giving Congress the power to protect the rights of authors and inventors," referring to Article I, Section 8 of the Constitution. These rights in intellectual property have been fundamental to Americans since our founding and have never been more important than they are today. Enforcement and protection of these rights is too important to be addressed piecemeal. In order to effect the greatest change, we must examine enforcement efforts from the top down and from the bottom up. I hope that with the help of our witnesses today, as well as that of other interested members of Congress, we can work to ensure not only the protection of American intellectual property, but the protection of the health and safety of the American public.

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Underwriters
Laboratories

Testimony of Underwriters Laboratories Inc. ®
Senate Committee on the Judiciary

Hearing On:
Protecting Consumers by Protecting Intellectual Property
June 17, 2008

Statement of
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Introduction

Chairman Leahy, Ranking Member Specter, and distinguished members of the Senate Judiciary Committee, thank you for this opportunity for Underwriters Laboratories Inc.® to appear before you today to provide our perspective on the dangers of IP infringement and the risks associated with counterfeit goods in the US marketplace. Counterfeiting is a serious threat to our economy and to the safety of US consumers. A variety of counterfeit products enter the stream of commerce everyday, many posing potentially serious fire and electrical hazards that endanger the American public. Based on UL's safety testing expertise and our experience with many of these dangerous products, the following testimony will offer our insights as to how additional resources and enforcement tools can help authorities more effectively fight IP crime.

Underwriters Laboratories & Anti-Counterfeiting Efforts

Founded in 1894, UL is an independent, not-for-profit standards development and product safety testing and certification organization. For 114 years, UL's mission has been the protection of human life and property from product risks and hazards. UL tests products in over 19,000 categories for compliance with standardized safety requirements. Once a product is determined to be in compliance with all applicable safety requirements, the manufacturer is authorized to apply the UL Mark. In 2007, an estimated 21 billion products entered the global marketplace carrying the UL Mark.

UL has built our reputation on the integrity of the UL Mark and what it represents to consumers. But the UL Mark, a registered Certification Mark, is being counterfeited – leaving consumers with a false sense of security about the safety of the products they purchase.

Recognizing that consumers, retailers, regulators, manufacturers and distributors look to the UL Mark to determine if products comply with relevant safety standards or regulatory requirements, UL established a team of professionals dedicated to protecting UL's intellectual property. Since 1995, UL's anti-counterfeiting team has worked with law enforcement agencies and has provided training to enforcement officials around the world on the identification of legitimate UL Certification Marks, as well as common elements shared by products bearing counterfeit Certification Marks.

IP Theft and Product Safety

There can be no doubt about the correlation between counterfeiting and product safety. In 2007 alone, UL issued warnings about fire extinguishers, smoke alarms, electrical cords, decorative light strands, lighting fixtures, grounding rods, power adapters, and surge protectors bearing counterfeit UL Certification Marks. Many of these are life safety products purchased specifically for the protection of life and property. With Certification Mark counterfeiting reaching into the fire protection and electrical sector, particularly in low-cost, high-volume goods, the risk of fire, shock, and other hazards become a serious life and safety threat to American consumers.

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The Electrical Safety Foundation estimates that 64.2% of counterfeit electrical goods were purchased at legitimate shops and retailers – higher than any other product type. This is troubling evidence that counterfeiters continue to penetrate the distribution chain with poor quality, noncompliant and hazardous products that endanger life and property. The core of product counterfeiting is profit margin; the cheaper the materials and components, the greater the potential profit. Counterfeiters have no regard for the safety and well being of the American consumer.

Common household extension cords are often targeted by certification mark counterfeiters. They can typically be purchased for under a dollar at discount stores across the country. To properly conduct current, electrical cords require copper wire of a certain thickness. Counterfeiters, to increase their profits, use extra plastic and so little copper that when electrical current is applied these products overheat, melt and can catch fire.

During 2007, the Newark seaport seized heavy-duty extension cords bearing fake safety certification trademarks, valued at $565,203. As is often the case, when UL tested samples the products bearing the counterfeit UL Mark, they failed to meet standardized requirements and created an unacceptable safety risk to the public. UL's goal is to continue working with enforcement agencies to prevent these products from ever reaching the hands of consumers.

Even more disturbing is the recent appearance of counterfeit Certification Marks on fire safety devices such as smoke detectors, heat detectors, sprinkler heads and fire extinguishers. Aggressive, pro-active measures need to be taken to prevent the entrance of these products into the marketplace. They need to be stopped before a fatal failure becomes another statistic.

Need for Collaboration

Enforcement authorities, victims of counterfeiting and piracy, and lawmakers are working together to combat these criminal activities. For over a decade, UL has worked closely with the Department of Justice, US Customs and Border Protection (CBP), and Immigration and Customs Enforcement (ICE), as well as state and local authorities, to push the identification and seizure of products bearing counterfeit UL Marks and to encourage prosecution of offenders to the fullest extent of the law. CBP seizures of products bearing counterfeit UL Certification Marks number in the thousands and have prevented millions of potentially hazardous products from reaching the US marketplace.

In 2005, the US Attorney's Office of the Southern District of Texas announced a sentence of 63 months in federal prison for a defendant found guilty of trafficking in counterfeit merchandise. This result can be attributed to the excellent work of CBP, ICE and the DOJ working in collaboration. UL, along with other rights holders, provided our support and cooperation.

In 2006, the US Attorney's Office of the Southern District of Florida announced that two defendants found guilty of trafficking in products bearing counterfeit marks were each sentenced to more than seven years in federal prison. The goods involved included

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batteries, extension cords, wallets, handbags, suitcases and many other items. Rights holders worked in partnership to provide the necessary information to assist in a successful prosecution. Again, government agencies collaborated and sent a strong message that counterfeiters that compromise the safety of American citizens will be pursued and punished.

UL's Anti-Counterfeiting Program, with support from the DOJ and other government and law enforcement agencies, has achieved some success combating the serious and growing threat of product counterfeiting. However, additional resources for such groups are necessary in order to continue this positive track record. With national security concerns such as terrorism stretching our import safety authorities' time and resources, it is important for the United States to maintain its commitment to safeguarding the public from hazardous counterfeit products.

The Plan Forward

Additional staffing and resources for DOJ and FBI, with dedicated personnel allocated to combating IP crimes, would go a long way towards meeting this commitment. Without stringent and effective consequences for counterfeiting products and certification marks, which pose direct threats to public safety, criminals will continue to choose the monetary rewards of cheating, ignoring the potential risks.

Staffing resources will also go a long way – dedicated FBI agents for existing or new Computer Hacking and Intellectual Property (CHIP) units, additional Assistant US Attorneys dedicated to the prosecution of IP cases, and staffing available for the formation of Ad Hoc task forces that can be mobilized quickly to address short-term situations and threats – towards combating these dangers.

We also encourage continued collaboration between government and the private sector, as this has proven successful in helping those who share an interest in IP protections drive towards a solution. Industry forums, hosted by DOJ, have brought together the government and industry to share experiences and solutions. These forums can serve as a model for new collaboration initiatives. Additionally, by authorizing increased resources to support cross-agency communication, this committee would strengthen the government's ability to prosecute organized fraud attempts, enforce existing IP laws, and educate consumers about the importance of intellectual property rights.

Conclusion

Protecting intellectual property protects lives. We strongly believe that this committee's full support of the measures we have highlighted for advancing IP protections will help protect the American consumer from the very real dangers that counterfeit products and certification marks pose. Through intergovernmental cooperation and improved enforcement resources and channels, we can secure not only our nation's economic interest and innovation, but can more importantly protect people and property in the very place they are meant to feel safe – their own homes.

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The Partnership for SAFE MEDICINES
SAFEMEDICINES.org

Consumer Protection Group Supports IP Enforcement to Combat Counterfeit Drugs

WASHINGTON (June 17, 2008) – The Partnership for Safe Medicines, a group of organizations and individuals dedicated to protect consumers from counterfeit medicines, issued the following statement regarding today's Senate Judiciary Committee hearing on "Protecting Consumers by Protecting Intellectual Property."

The Partnership for Safe Medicines applauds the Committee for recognizing that enforcement of intellectual property (IP) laws are an important way to combat the sale of unsafe or substandard products, such as counterfeit pharmaceuticals. Time and time again, we have seen imitations of FDA- approved drugs contaminated with harmful or unsafe materials, as well as counterfeits containing nonstandard amounts of active ingredients that affect the integrity of the medication.

One of the Partnership's core principles for drugs safety is that we must unify in the fight against counterfeit drugs. We believe the United States needs to be a leader in this global fight. We must advocate for better cooperation between government agencies here within the United States, as well as with our counterparts around the world, in order to prosecute the unscrupulous counterfeiters who do not hesitate to use foreign, even toxic, materials in their products.

Counterfeit drugs defraud consumers and deny ill patients therapies that can alleviate suffering and save lives. The harm and fatalities from counterfeit and contraband medicines must stop. The Partnership supports increasing criminal penalties against the perpetrators of counterfeit medicines to reflect the gravity of their offenses. Additionally, we endorse granting the FDA the authority to destroy unapproved drugs entering the United States rather than returning them to the criminals who sent them here.

If we truly want to avoid another deadly incident of failed drug safety, we urge Congress to take this opportunity to further address the vulnerabilities threatening the safety of our prescription drugs. To learn more about how we can protect our supply chain, regulate online pharmacies, fight counterfeit drugs and other principles of drug safety, please visit SafeMedicines.org—because counterfeit drugs are unsafe at any cost.

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About the Partnerships for Safe Medicines
The Partnership for Safe Medicines is a group of organizations and individuals that have policies, procedures, or programs to protect consumers from counterfeit or contraband medicines. To join us in our stand against counterfeit drugs or obtain your own copy of the *Principles for Drug Safety* doctrine, please visit www.SafeMedicines.org.

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The Partnership for
SAFEMEDICINES

Principles for Drug Safety

Every consumer should feel secure the medicines they purchase are of the highest quality. Drug safety can be compromised by taking medications past the expiration date or if they are stored or handled improperly. Imitations of FDA approved drugs could be contaminated with harmful or unsafe materials. Counterfeits might contain non-standard amounts of active ingredients that affect the integrity of the medication.

The Partnership for Safe Medicines has developed the following principles to support quality assurance programs and establish a drug distribution system that is without compromise.

Protect Our Supply Chain

- We believe there is strong need for strict, rigorous regulatory oversight of imported pharmaceuticals, including the regulation of the storage throughout the distribution system of imported pharmaceuticals.
- We support a dramatic and sustained increase in funding for the FDA in order to increase inspections of foreign facilities that manufacture drug products or components of drug products sold in the United States. Additionally, the FDA should be empowered to inspect distribution facilities.
- We endorse establishing permanent FDA field offices in China, India and other key exporting countries staffed with both inspectors and criminal investigators.
- We advocate the development and implementation of a standardized drug pedigree program at a national level.

Regulate Online Pharmacies

- We value the rigorous oversight and standards that govern traditional pharmacies in the United States and believe all online drug sellers should be held to the same standards.
- We endorse the Verified Internet Pharmacy Practice Site (VIPPS) accreditation program created by the National Association of Boards of Pharmacy.
- We believe all Internet drug sellers, regardless of which state or country they are based in, must comply with the pharmaceutical licensing and survey requirements for every state they send pharmaceuticals.
- We advocate that no one should be able to purchase prescription drugs, including controlled substances, over the Internet without a valid prescription.

Unify in the Fight Against Counterfeit Drugs

- We believe the United States needs to be a leader in the global fight against counterfeit drugs.
- We recognize that counterfeit drugs, tainted medicines, and rogue online pharmacies are a global problem that requires an international solution.
- We advocate for international cooperation between government agencies around the world in order to prosecute the unscrupulous counterfeiters who do not hesitate to use foreign, even toxic, materials in their products.
- We support increasing criminal penalties against the perpetrators of counterfeit medicines to reflect the gravity of their offenses.
- We endorse granting the FDA authority to destroy unapproved drugs entering the United States rather than returning them to the criminals who sent them here.

Thank you for your introduction, Mr. Chairman. On behalf of the nearly 120,000 employees of Johnson & Johnson, thank you for the opportunity to speak here today.

Let me briefly tell you about Johnson & Johnson.

Our consumer companies are responsible for many familiar personal products used in baby care, skin care, oral care, wound care and women's health, including familiar brands such as JOHNSON'S* Baby and BAND-AID*. We also market an extensive line of over-the-counter medicines that include such well-known names as TYLENOL® and MOTRIN®.

Our device companies supply professional products to physicians, surgeons, consumers, and laboratories for many uses, including patient care, wound closure, diagnosis, blood testing and surgery. Surgical implants, needles, sutures, endoscopic instruments, orthopedic products, infection control products, cardiovascular monitoring and vascular access products are among our wide array of products used by medical professionals.

Our pharmaceutical companies develop and have brought to market prescription products including products for psychiatry, infection control, cancer, immunotherapy, family planning, and cardiovascular disease. We discover and manufacture both traditional and small molecule medicines, as well as biotechnology-derived products.

Counterfeit healthcare products present an extraordinary risk to patients and consumers.

According to the FDA, the United States pharmaceutical supply chain is one of the safest in the world. Nonetheless, counterfeiting of healthcare products is a growing concern for society. The World Health Organization estimates that 8-10% of pharmaceutical products outside the United States are counterfeit. In some countries, counterfeit products may represent 50% of medicines in the marketplace.

Until recently lifestyle and biological products have been primary targets of counterfeiters. Counterfeit heart, arthritis, asthma, AIDS, diabetes, and cancer medications have been found. Even relatively low cost consumer products such as shampoo and toothpaste have been counterfeited.

Medical devices are not immune to counterfeiting. A Gray Sheet article dated June 2, 2008, stated - - "Counterfeiting of medical devices, including sophisticated implantable devices, is a growing threat to patient safety and manufacturers' reputations". Medical device operating companies of Johnson & Johnson have experienced counterfeit medical devices.

The Internet is becoming the marketplace of choice for the counterfeiter. Counterfeit pharmaceutical products can be purchased from a wide variety of unregulated Internet pharmacies. These Internet pharmacies are in many cases shams, selling potentially ineffective or unsafe products. The counterfeiter can easily sell their products via a website and distribute them into the US via the US postal or private express mail services to their unsuspecting customers. Counterfeit and diverted medical devices can be purchased via on-line auction sites.

These scams are so widespread that according to the Pharmaceutical Security Institute, "seizures of bogus prescription medicines jumped 24 percent to 1,513 incidents in 2007, and illicit versions of 403 different prescription drugs were confiscated in 99 countries." The FDA Office of Criminal Investigations and border inspection officials make many seizures of illicit products each year, but the federal resources cannot catch every package containing an illegal product.

Another avenue for counterfeiters to introduce fakes or substandard product into the supply chain is diversion. Diversion refers to merchandise that is distributed into markets other than originally intended in violation of a contract, law or regulation. Diverted product, commonly referred to as "grey market" product, is frequently past dated or expired, had been previously marked for

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destruction, had not been properly stored, or is counterfeit product. When product is diverted, authentic and grey market products travel together through the supply chain creating confusion. For example, a hospital could receive legitimate and diverted product in the same shipment. The diverted product is stocked on the same shelf beside the legitimate product. A surgeon could unknowingly select the diverted product and implant a substandard product into the patient. The patient could experience a wide range of medical complications.

Counterfeiters show total disregard for the safety of consumers, patients, doctors and nurses who unwittingly encounter the counterfeit product. Counterfeiters don't care about product quality, safety, or efficacy. People who use a counterfeit healthcare product run the risk of a wide variety of medical problems ranging from experiencing no therapeutic benefit... to new illnesses... and even death.

Counterfeiters have no regard for intellectual property rights. They take advantage of countries with gaps in intellectual property laws or where enforcement of IP laws is nonexistent or lax. Some countries do not enforce IP laws for products made for export only. These countries provide the counterfeiter a safe haven for their operations. The active ingredient can be manufactured in one country, exported to a second where the product is packaged, exported to a third country where it is labeled and finished packaged, and exported for final sale.

Both healthcare manufacturers and governmental regulators have begun taking action to combat counterfeiting and to protect our consumers and patients. Many healthcare manufacturers have invested in measures to tighten the security of supply chains and products. These measures are multifaceted with IP and trademark protection being just two key areas of focused effort.

While much work remains, here are some examples where manufacturers are focusing their efforts:

- Renegotiating trade agreements with authorized distributors of record (ADR's) to ensure ADR's only buy directly from the manufacturer or a manufacturer's approved source.
- Conducting market monitoring activities and auditing trading practices to identify sources of illicit trade.
- Collaborating with customs and police to investigate suspected cases of counterfeit or tampering activities, and aggressively prosecuting the offenders.
- Working with governmental agencies to ensure trademark and IP laws are enforced and prosecuting infringements.
- Applying overt and covert features to products and product packaging to aid in product identification.
- Deploying communication programs to healthcare professionals and downstream supply chain partners encouraging them to buy from approved sources and alerting them to the dangers of counterfeit or tampered products.
- Investigating and piloting track & trace and pedigree systems to communicate the product's chain of custody. These systems are intended to improve visibility into the supply chain and gain greater clarity into where products have been and where they are moving to in the supply chain.

Pedigree documents the chain of custody of a specific product. Regulators have been working on regulations at state and federal levels, and in other countries requiring pedigree on pharmaceuticals. Over 30 U.S. states have enacted pharmaceutical pedigree legislation. Countries as diverse as Turkey, Japan, Brazil, Serbia and Slovenia have, or are considering, legislation requiring tracking and tracing of pharmaceutical products. As a result, we have a patchwork quilt of pedigree laws and regulations that could defeat the purpose of improving supply chain security.

We believe that the Senate Judiciary Committee should be interested in eliminating the complexity of multiple pedigree laws, which may result in fraudulent - and even counterfeit - pedigrees, and in its place implement a simple and potentially effective solution: the electronic

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pedigree (ePedigree). Making distributors produce ePedigrees for law enforcement when products are questioned would increase the effectiveness of law enforcement in combating counterfeiting. Immediate information about the authenticity of a product puts powerful information in the hands of law enforcement for enforcement action. Within the US, a federal standard is required for electronic pedigree. This is an area where the federal government can and should take the lead.

We cannot over emphasize that the integrity of the pharmaceutical and medical device supply chain is essential to the well being of all of our citizens. Patients and consumers rely on our medicines, medical devices and personal products everyday to improve the quality of their lives and, in many cases, to save their lives. Healthcare manufacturers depend upon the integrity of our supply chain to ensure that patients and consumers receive genuine products from approved sources.

As the healthcare supply chain becomes increasingly global, coordination across manufacturers, distributors, pharmacies, hospitals, and a wide variety of governmental agencies will be imperative to ensure the integrity of the healthcare supply chain.

There is a critical and concerted effort to maintaining supply chain integrity across the industry. Yet, as counterfeiters increase their activity and sophistication in creating fake products, industry must also increase resources to address this criminal activity. This requires a diversion of industry resources that otherwise would be applied to drive medical innovations that will address some of today's most pressing health care challenges.

Here are some examples where we believe Congress could encourage governmental agencies to work together to protect patients and consumers from counterfeit products.

Congress should....

- Pass legislation that would enable the FDA to establish industry-wide implementation dates for federal pedigree standards. The FDA should be encouraged to work with state and international regulators to develop effective, practical pedigree and track & trace standards for the United States and globally.
- Support a review of the FDA's Office of Criminal Investigation's procedures and organizational capacity for handling enforcement actions. OCI is an important FDA resource to help manufacturers combat counterfeit products.
- Encourage the FDA's regulatory and OCI divisions to develop a common approach for working with the healthcare industry on investigation and enforcement actions.
- Enact legislation that ensures manufacturers can protect their products no matter where they are in the supply chain so that consumers are protected from unwittingly receiving adulterated products. Including requiring that all returned product be sent back to the manufacturer.
- Provide sufficient resources to the Patent and Trademark Office to work with their international counterparts to ensure proper IP protection and the enforcement of existing IP laws.
- Sponsor a nation-wide awareness campaign aimed at consumers to warn them about the dangers of opportunistic purchases of medications from non-licensed health care providers.

As I stated earlier in my comments, we are fortunate to be living in the United States and to be served by one of the most secure healthcare supply chains. Johnson & Johnson believes it is our responsibility to help ensure that all people receive genuine, unadulterated products from trusted authorized trading partners. All people deserve the right to be protected from the dangerous effects of counterfeit products.

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Johnson & Johnson is pleased to work with Congress, the FDA and any other governmental agencies whether Federal, State or International to develop effective laws and regulations to protect patients and consumers from counterfeit products. We are ready to make our company experts available to these legislative and regulatory efforts.

Thank you for allowing Johnson & Johnson to share our perspective on this critical issue with you today. If we can be of any further assistance, we are available to help this committee. I am happy to answer your questions.

Testimony
Jeff Thurnau, Patent Counsel
Gates Corporation

Senate Judiciary Committee
Protecting Consumers by Protecting Intellectual Property
June 17, 2008

Chairman Leahy, Ranking Member Specter, other distinguished Members of the Judiciary Committee, thank you so much for this opportunity to testify on "Protecting Consumers by Protecting Intellectual Property." I am Jeffrey Thurnau, Patent Counsel for Gates Corporation. Gates shares the bipartisan view of this Committee that much more needs to be done in the Congress and the country to combat counterfeiting. We appreciate your leadership on the range of global intellectual property protection challenges facing our country and support your effort to pass legislation this year on this important topic.

Headquartered in Denver, Colorado, Gates has 5,000 employees at 25 facilities across America. We are one of the world's largest manufacturers of industrial and automotive products, systems and components.[1] We are proud to work with the Motor & Equipment Manufacturers' Association (MEMA)[2], our voice in Washington, DC on motor vehicle parts issues. MEMA's Brand Protection Council leads industry efforts on brand protection and intellectual property issues.

We at Gates are pleased to be part of an innovative American auto parts industry. Motor vehicle parts suppliers are the nation's largest manufacturing sector, directly employing 783,100 U.S. workers and contributing to 4.5 million private industry jobs across the nation. Suppliers manufacture the parts and develop the technology used in the domestic production of more than 11 million new cars and trucks annually, as well as the aftermarket products necessary to repair and maintain over 247 million vehicles on the road today. Strong intellectual property protections are critical to the success of Gates Corporation and our entire industry.

Today I am going to focus my comments on the safety implications of counterfeit automotive parts for the American people. I will begin with an overview of the global counterfeit challenges facing the auto parts industry, give you an idea of the particular counterfeit issues faced by Gates Corporation and then offer some ideas, legislative and

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[1] Gates Corporation is headquartered in Denver, Colorado, where it was founded in 1911. Gates is part of the Industrial & Automotive group of Tomkins plc, a global engineering group listed on both the London (TOMK) and New York (TKS) stock exchanges

[2] The Motor & Equipment Manufacturers Association (MEMA) represents almost 700 companies that manufacture motor vehicle parts for use in the light vehicle and heavy duty original equipment and aftermarket industries.

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otherwise, that would help combat the intellectual property piracy that face our company and our industry.

Protection of Gates intellectual property is critical to the success of our high end business model. Our aim is to continually develop the most innovative technology in our market sectors, patent the products that our technology creates, then lead the market in those sectors. This approach allows us to create high-wage, high-skill jobs in America. For example, at Gates, we are developing a range of energy efficiency solutions that reduce the cost of operating motor vehicles, reduce the impact on our environment, and reduce dependency on foreign oil. However, every time our technology and the integrity of our brand and technology is violated by intellectual property pirates our business model and industry leadership are further compromised. Clearly, strong intellectual property protection benefits Gates Corporation, our communities, our customers, and ultimately the American people.

The enshrining of patent protection in our Constitution more than 200 years ago signaled that intellectual property protection would be a critical component of American innovation going forward. Over time, the value of strong IP protection was recognized by our allies around the world. The expectation that innovation and hard work will be rewarded and protected has provided the incentive for companies such as Gates to invest in developing new products and technologies, thus fueling the global economic engine. Intellectual property owners of high-end products such as those Gates manufacturers must have the ability to protect their developments from piracy in all markets, not just in those of developed nations. The design and enforcement of comprehensive intellectual property laws must be a top priority to spur the creation of new technology and to protect that investment throughout a product's viable life. Clearly, protecting IP is a key factor in any nation's competitiveness.

A. Economic Impacts

The magnitude of the overall global counterfeit problem is significant. Global counterfeiting across the range of sectors in 2003 was estimated at $500 billion. More startling is that fact that this figure represents five to seven percent of total world trade volume.

Pirated movies and music are often the first things that come to mind for many people when they think about IP infringement. International intellectual property protection is about much more than defending Hollywood and other copyright industries, though that will always be an important component of the battle. It is also about the safety of a wide variety of consumer products such as pharmaceuticals and motor vehicle parts whose industries are represented at the hearing today. IP protection is critical to the health and safety of American families as well as the economic health of the industries that manufacturer these goods and the communities that support these industries.

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Counterfeit parts and components for cars, trucks, buses and commercial vehicles pose a critical problem to the American economy and the supplier industry because of the wide range of counterfeit products manufactured and trafficked worldwide. Counterfeit goods cost motor vehicle suppliers at least $3 billion in the United States and $12 billion globally in lost sales. These losses correlate to at least 250,000 fewer motor vehicle supplier manufacturing jobs nationwide. Please note that these are conservative numbers based on a 1997 Federal Trade Commission study.

About 80 percent of all pirated goods seized at U.S. borders originate in China. And while it is clear in our industry that more pirated parts come from China than any other nation, we do face significant challenges from Russia, India and many other nations. The temptation might be to criticize the Chinese government for lack of intellectual property enforcement but our experience would say that is inaccurate and counterproductive. The counterfeiters that we deal with are for the most part rogue operators, criminals. The Chinese government pursues those criminals when our company presents evidence of our trademarks being violated. Enforcement issues are often caused by a lack of resources, particularly at the provincial and city level.

Since China joined the World Trade Organization in 2001, the government has upgraded intellectual property protections to world standards. In addition, we are getting data that enforcement is improving in China. For example, during a recent visit Gates representatives met with Chinese customs officials in four provinces. From these meetings, we understand that customs official's job performance is now linked to seizures of counterfeit goods. Gates is in the process of providing more detailed background information to the officials to support their important work directed to intercepting the flow of counterfeits good out of China.

B. Gates Corporation and Industry Intellectual Property, Health and Safety Issues

Even more disturbing than the economic impact of counterfeit motor vehicle parts is the fact that vehicle performance and safety is severely impacted by counterfeit products such as brakes and brake pads, brake fluid, tires, belts, and automotive lighting. The use of counterfeit parts can result in sudden, catastrophic engine failure, brake failure, or other system malfunction. Counterfeit parts can also fail to meet motor vehicle safety standards, which could cause injury or death.

Trademark or brand infringement is the most immediate problem we face at Gates Corporation since it is the most direct and easiest method for pirates to get their counterfeit goods into the market. Stolen trademarks give instant market credibility to pirated goods. The consumer who purchases the product with the pirated trademark faces immediate risk of loss of product and/or serious adverse safety impacts.

Another method used by pirates is to copy trade dress or the unique appearance of product packaging. Usually the pirates do not make perfect copies, instead making the packaging confusingly similar, to allow them to disingenuously claim that they are not infringing. The average consumer cannot always distinguish the two packages and

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erroneously concludes that the counterfeit package is also an authentic product. The pirate preys on the market recognition of the trade dress owner. Further, the infringed trademark owner may be faced with honoring warranty claims for pirate products or risk loss of customer confidence and loyalty. This is an added and unanticipated cost of doing business.

Counterfeit auto parts create real safety consequences for consumers. Gates is a major manufacturer of a range of belts used in motor vehicles. Timing belts allow the internal components of the engine to operate with proper timing; namely, the valves and pistons. A counterfeit timing belt may wear and fail prematurely causing serious cost, health, and safety ramifications for consumers.

We have tested pirated timing belts and have found they have a significantly shorter life when compared to our products. Unexpected and premature failure of a timing belt would be highly problematic to a motorist since it would result in the destruction of the engine for all practical purposes. Consequently, a broken timing belt could strand a motorist and cost several thousand dollars to repair the damaged engine. And a motorist stranded on the beltway in Washington, DC, may face serious hazards as he tries to cross multiple lanes to safety.

Let me give you some tangible examples of piracy involving Gates' belts that provide some additional background.

1. In March 2008, Taiwan customs notified Gates local counsel of a suspect shipment of 700 timing belts arriving from China. Gates local counsel immediately coordinated with Taiwan customs to advance the case. The case has been referred by Taiwan customs for further legal action. The name of the importer has not yet been shared with Gates. I think this is a good example of how governments around the world are helpful in the intellectual property battle. The fact is that most governments want to enforce the law against rogue operators.

2. In November 2006, in Puerto Rico, belts were sold to Gates representatives by a rogue operator for significantly less than the market price in legitimate outlets. This pirate distributor operated out of his home, using a trailer as his warehouse. The pirate also kept a booth at flea market in Arecibo. Gates investigators tested several of the belts at the Gates facility in Siloam Springs, Arkansas. After receiving a cease and desist letter, the pirate disclosed a supplier in China. The pirate had in his possession over 600 belts. The pirate also disclosed that he sold pirate belts on various internet sites. The pirate ultimately agreed to suspend sales as well as disclose the infringing manufacturer in China.

3. In December 2006, in China, a product analysis revealed the Gates logo was erased from the product and replaced with a trademark having the same form and font. A cease and desist was sent July 27, 2007. The case was settled after the infringer agreed not to use any Gates trademarks, not to re-label product, not to

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sell any product with confusingly similar trade marks, and agreed that the pirate's name will not be used in any form that can be confused with Gates; such as an oval or a script "G".

4. In October 2006, in Poland, suspect timing belts were purchased by Gates associates from a distributor in Poland. Gates filed a criminal complaint with Warsaw police, who raided the defendant's facility and seized other belts. The distributor admitted buying from a Chinese source. Criminal proceedings are on-going; with the Court appointing an expert to determine damages and if counterfeit belts would threaten the lives of drivers or passengers. Civil action also filed in Poland obliges the defendant to withdraw the belts from the market and to destroy the counterfeit belts.

C. Industry Experience

Counterfeit issues are wide-spread in the motor vehicle parts industry. For example, another MEMA member, Bendix Commercial Vehicle Systems LLC , headquartered in Elyria, Ohio, manufactures commercial vehicle safety technology and braking systems. Due to the broad scope of the products that they design and manufacture, Bendix has been faced with a wide range of counterfeit products, many of which are safety critical, not only for operation of the commercial vehicle on which these components are installed, but also for those who share the highways with these vehicles. Of particular note was a recent reported case involving air dryers for school buses. Air dryers are a critical component for vehicle braking systems. In this situation, a school bus equipped with what was thought to be a replacement genuine Bendix air dryer was causing a loss of air pressure and erratic operation of the vehicle, placing the safety of the students riding the bus in jeopardy.

D. Potential Solutions

You can see that a company like Gates faces a myriad of challenges to its intellectual property around the globe. In general, we strongly support what this Committee is attempting to do to combat the problem by encouraging better coordination by Federal agencies, greater penalties to infringers and greater resources for enforcement. Specifically, I urge you to consider some of the following ideas to address the range of concerns that I have expressed today on behalf of Gates and the Motor & Equipment Manufacturers' Association.

These include:

- Better coordination of Executive Branch Enforcement efforts. I urge the committee to address the shortcomings in current domestic and international enforcement practices by better coordinating federal enforcement efforts in a government-wide approach. More broadly, there are at least three good bills currently being considered by the Congress that if enacted, could make a real positive difference in protecting intellectual property:

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- S. 522, sponsored by Senators Bayh and Voinovich streamlines Executive Branch coordination, ensuring that the range of relevant IP agencies and policy issues are covered.
- H.R. 4279 which passed the House in May, includes a coordinating IP czar at the Department of Justice as well as additional enforcement funding and increased penalties for infringement.
- And last, but certainly not least, Mr. Chairman, your legislation S. 2317 offers some very constructive ideas in this arena. For example, the increased penalties in this legislation for trafficking in counterfeit labels or packaging are very welcome by our industry. Again, we look forward to working with you to perfect this legislation and to help you pass it this year.

- Protection for the range of IP tools internationally is a lead policy principle for any IP enforcement legislation. The inclusion of protections for trademarks, trade dress, patents, and copyrights is a critical component of any legislation that passes the Congress.

Other important objectives for legislation include:

- Additional resources in the traditional international trade agencies of Commerce and USTR to better equip these agencies for battle.

- Increased enforcement resources at the Department of Homeland Security and the Department of Justice as well as more personnel, training and technology to increase detection of counterfeit products in US ports and throughout the supply chain.

- Additional resources in the traditional international trade agencies of Commerce and USTR to better equip these agencies for battle.

- Increased enforcement resources at the Department of Homeland Security and the Department of Justice; more personnel, training and technology to increase detection of counterfeit products in US ports and throughout the supply chain.

- Strengthened border enforcement and tougher penalties for violations, including efforts to improve communications and coordination between and within agencies that patrol our borders.

- Increased investigations and arrests by Federal agents.

- Increased prosecutions for counterfeiting and other intellectual property rights crimes in our courts.

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- Enhanced cooperation with the law enforcement agencies of other like-minded countries, leading to more vigorous enforcement of the existing IP laws of those countries.

Mr. Chairman, thank you again for the opportunity to testify. I welcome any questions that the Committee might have.

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United States Government Accountability Office

GAO

Testimony
Before the Committee on the Judiciary, U.S. Senate

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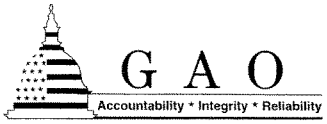
INTELLECTUAL PROPERTY

Leadership and Accountability Needed to Strengthen Federal Protection and Enforcement

Statement of Loren Yager
Director, International Affairs and Trade



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June 17, 2008

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Highlights

Highlights of GAO-08-921T, a testimony before the Committee on the Judiciary, U.S. Senate

INTELLECTUAL PROPERTY

Leadership and Accountability Needed to Strengthen Federal Protection and Enforcement

Why GAO Did This Study

U.S. government efforts to protect and enforce intellectual property (IP) rights domestically and overseas are crucial to preventing billions of dollars in losses to U.S. industry and IP rights owners. The illegal importation and distribution of IP-infringing goods also poses a threat to the health and safety of U.S. citizens. However, the challenges involved in IP protection are significant and require effective coordination among a wide range of policy and law enforcement agencies. Multiple agencies work to protect IP rights, and they coordinate their efforts through certain coordination bodies as well as an executive-branch strategy called the Strategy Targeting Organized Piracy (STOP).

This testimony addresses two topics: the need for (1) greater leadership and permanence in the national IP enforcement strategy and coordination structure; and (2) improvement in key agencies' criminal IP enforcement data collection and analysis. It is based on prior GAO work conducted from 2003 to 2008.

What GAO Recommends

Previous GAO reports recommended, among other things, improvements in the strategic planning and coordination of IP enforcement efforts and in agency collection and analysis of IP enforcement data. The affected agencies generally agreed with our recommendations and some have begun taking steps in response.

To view the full product, including the scope and methodology, click on GAO-08-921T. For more information, contact Loren Yager at (202) 512-4347 or yagerl@gao.gov.

What GAO Found

The coordinating structure that has evolved for protecting U.S. intellectual property rights lacks leadership and permanence, presenting challenges for effective long-term coordination. The National Intellectual Property Law Enforcement Coordination Council (NIPLECC), created by Congress in 1999, serves to coordinate IP protection and enforcement across agencies; and STOP, initiated by the White House in 2004, is the strategy that guides the council. NIPLECC has struggled to define its purpose and has an image of inactivity within the private sector. It continues to have leadership problems despite enhancements made by Congress in 2004 to strengthen its role. STOP, which is led by the National Security Council, has a more positive image compared to NIPLECC, but lacks permanence since its authority and influence could disappear after the current administration. While NIPLECC adopted STOP in 2006 as its strategy for protecting IP overseas, its commitment to implementing STOP as a national strategy remains unclear, creating challenges for accountability and long-term viability.

Agencies within the Departments of Justice, Homeland Security, and Health and Human Services that play a role in fighting IP crimes through seizures, investigations, and prosecutions need to improve their collection and analysis of IP enforcement data. IP enforcement is generally not the highest priority for these agencies, given their broad missions, but addressing IP crimes with a public health and safety risk, such as counterfeit pharmaceuticals, is an important activity at each agency. Federal IP enforcement actions generally increased during fiscal years 2001–2006, but the agencies have not taken steps to assess their achievements. For example, despite the importance assigned to targeting IP crimes that affect public health and safety, most agencies lack data on their efforts to address these types of crimes. Also, most have not systematically analyzed their IP enforcement statistics to inform management and resource allocation decisions or established IP-related performance measures or targets. In addition, the National Intellectual Property Rights Coordination Center, created to coordinate federal IP investigative efforts, has not achieved its mission. Participating agencies have lacked a common understanding of the center's purpose and their roles in relation to it, and staff levels have declined.

United States Government Accountability Office

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to appear today before the Judiciary Committee to discuss our work on U.S. efforts to protect and enforce intellectual property (IP) rights. U.S. government efforts to protect and enforce intellectual property rights domestically and overseas are crucial to preventing billions of dollars in losses to U.S. industry and IP rights owners. Along with the costs to the U.S. economy, the illegal importation and distribution of counterfeit and pirated goods poses a threat to the health and safety of U.S. citizens. However, the challenges involved in IP protection are significant, and include the technological advances that facilitate piracy as well as the need for effective coordination among a wide range of policy and law enforcement agencies.

In my statement today, I will address two topics: the need for (1) greater leadership and permanence in our national IP enforcement coordination structure and strategy; and (2) improvement in key agencies' criminal IP enforcement data collection and analysis.

My remarks are based on a variety of assignments that GAO has conducted on intellectual property protection over the past 5 years.[1] In this research, we performed work at multiple U.S. agency headquarters in Washington, D.C., agency field offices, and U.S. ports across the country. We reviewed key U.S. government IP reports and relevant agency documents, including IP enforcement data. In addition, we met with representatives from multiple industry associations and companies that are affected by IP violations. We conducted our work from June 2003 through March 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Summary

The current U.S. government coordinating structure that has evolved for protecting and enforcing U.S. intellectual property rights lacks leadership and permanence, presenting challenges for effective and viable

[1]See Related GAO Products at the end of this statement for a list of GAO reports and testimonies on intellectual property protection since 2004.

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coordination for the long term. The National Intellectual Property Law Enforcement Coordination Council (NIPLECC), created by Congress in 1999, serves to coordinate IP protection and enforcement across multiple agencies; and the Strategy for Targeting Organized Piracy (STOP), initiated by the White House in 2004, is the strategy that guides the council. NIPLECC has struggled to define its purpose and retains an image of inactivity within the private sector. It continues to have leadership problems despite enhancements made by Congress in December 2004 to strengthen its role. In contrast, STOP, which is led by the National Security Council, has a more positive image compared to NIPLECC, but lacks permanence since its authority and influence could disappear after the current administration. While NIPLECC adopted STOP in February 2006 as its strategy for protecting IP overseas, its commitment to implementing STOP as a national strategy remains unclear, creating challenges for accountability and long-term viability.

Agencies within the Departments of Justice (DOJ), Homeland Security (DHS), and Health and Human Services (HHS) that play a role in fighting IP crimes need to improve their collection and analysis of IP enforcement data. Federal IP enforcement functions include seizures, investigations, and prosecutions. IP enforcement is generally not the highest priority for these agencies, given their broad missions, but addressing IP crimes with a public health and safety risk, such as counterfeit pharmaceuticals, is an important enforcement activity at each agency. Federal IP enforcement actions generally increased during fiscal years 2001–2006, but the agencies have not taken steps to assess their achievements. For example, despite the importance assigned to targeting IP crimes that affect public health and safety, we found that most agencies lack data to report on or analyze their efforts to address these types of crimes. Also, most have not systematically analyzed their IP enforcement statistics to inform management and resource allocation decisions or established IP-related performance measures or targets to assess their achievements. We also found that the National Intellectual Property Rights Coordination Center, an interagency mechanism created to coordinate federal investigative efforts related to IP crimes, has not achieved its mission, in part because participating agencies have lacked a common understanding of the center's purpose and their roles in relation to it, and staff levels have declined.

Background

Intellectual property, for which the U.S. government provides broad protection through means such as copyrights, patents, and trademarks, plays a significant role in the U.S. economy, and the United States is an

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acknowledged leader in its creation. According to the U.S. Coordinator for International Intellectual Property Enforcement, industries that relied on IP protection were estimated to account for over half of all U.S. exports, represented 40 percent of U.S. economic growth, and employed about 18 million Americans in 2006. These industries must compete with the global illicit market that is being spurred by economic incentives such as low barriers to entry into counterfeiting and piracy, high profits, and limited legal sanctions if caught. In addition, technology has made reproduction and distribution of some products more accessible, and some countries, particularly China, continue to have weak IP enforcement despite U.S. efforts.

Multiple federal agencies undertake a wide range of activities to protect and enforce IP rights. The Departments of Commerce and State, the U.S. Trade Representative (USTR), the Copyright Office, the U.S. International Trade Commission, and the U.S. Patent and Trademark Office play a role in IP protection. Key federal law enforcement agencies that play a role are DHS's Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE), and DOJ's Criminal Division, U.S. Attorneys Offices, and the Federal Bureau of Investigation (FBI). HHS's Food and Drug Administration (FDA) and the U.S. International Trade Commission also help enforce IP rights.

U.S. IP Enforcement Structure and Strategy Need Stronger Leadership and Permanence

The current coordinating structure for U.S. protection and enforcement of intellectual property rights lacks clear leadership, hampering the effectiveness and long-term viability of such coordination. Created in 1999 to serve as the central coordinating structure for IP enforcement across federal agencies, NIPLECC has struggled to define its purpose, retains an image of inactivity within the private sector, and continues to have leadership problems despite enhancements made by Congress in December 2004 to strengthen its role. In addition, in July 2006, Senate appropriators expressed concern about the lack of information provided by NIPLECC on its progress.

In contrast, the presidential initiative called STOP, which is led by the National Security Council, has a positive image compared to NIPLECC, but lacks permanence, since its authority and influence could disappear after the current administration leaves office. Many agency officials said that STOP has increased attention to IP issues within their agencies, in the private sector, and abroad; they attributed this to the fact that STOP came out of the White House, thereby lending it more authority and influence. While NIPLECC adopted STOP as its strategy for protecting IP overseas in

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February 2006, its commitment to implementing STOP remains unclear, creating challenges for accountability and long-term viability. For instance, neither NIPLECC's September 2006 annual report nor its most recent January 2008 report explain how the NIPLECC principals plan to carry out their oversight responsibilities mandated by Congress to help ensure a successful implementation of the strategy. In addition, the STOP strategy document has not been revised to mention NIPLECC's oversight role.

STOP is a first step toward an integrated national strategy to protect and enforce U.S. intellectual property rights, and it has energized agency efforts. However, we found that STOP's potential as a national strategy is limited because it does not fully address important characteristics of an effective national strategy. For example, its performance measures lack baselines and targets that would allow policymakers to better assess how well the activities are being implemented. In addition, the strategy lacks a risk management framework and a discussion of current or future costs—important elements for policymakers to effectively balance the threats from counterfeit products with the resources available. STOP does not specify who will provide oversight and accountability among the agencies carrying out the strategy, but it does identify organizational roles and responsibilities with respect to individual agencies' STOP activities. We found individual agency documents that include some key elements of an effective national strategy, but they have not been incorporated into the STOP documents. This lack of integration underscores the strategy's limited usefulness as a management tool for effective oversight and accountability by Congress as well as the private sector and consumers whom STOP aims to protect. In our November 2006 report on this subject, we made two recommendations to clarify NIPLECC's oversight role with regard to STOP and to improve STOP's effectiveness as a planning tool and its usefulness to Congress. The U.S. IP Coordinator, who heads NIPLECC, concurred with our recommendations and said NIPLECC has taken some steps to address them.

Key Agencies Need Better Data Collection and Analysis to Strengthen IP Enforcement Efforts

The five key federal agencies that play a role in fighting IP crimes—DOJ's U.S. Attorney's Offices and the FBI; DHS's CBP and ICE; and HHS's FDA—need to improve their collection and analysis of IP enforcement data. IP enforcement activities are generally a small part of these agencies' much broader missions, and IP enforcement is not the agencies' top priority. However, within their IP enforcement activities, these agencies have given enforcement priority to IP crimes that pose risks to public health and safety, such as counterfeit pharmaceuticals, batteries, and car parts. The

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key agencies have various IP enforcement functions: CBP is responsible for seizing counterfeit goods at U.S. ports of entry; ICE, the FBI, and FDA share responsibility for investigating crimes, with FDA focusing solely on IP crimes that present public health and safety risks; DOJ is responsible for prosecuting alleged violations. CBP and ICE address IP enforcement as part of their legacy efforts to combat commercial fraud, but their top mission is securing the homeland. DOJ identifies IP enforcement as one of its top priorities, but the FBI does not. FDA's role is driven by its public health and safety mission, not IP enforcement per se.

Our review of agencies' enforcement statistics from fiscal year 2001 through 2006 found that many IP enforcement activities generally increased (with some fluctuations across fiscal years and type of enforcement action), but some did not. For example, the number of CBP seizure actions and the value of seizures have increased steadily between 2001 and 2006, with the estimated value of goods seized reaching about $155 million in 2006. However, CBP collected less than 1 percent of IP-related penalties assessed during those years. The number of arrests, indictments, and convictions by ICE, the FBI, and FDA also generally increased during that time. Finally, the number of DOJ IP prosecutions was around 150 per year before increasing to 200 in 2006. Of the approximately 1,500 defendants that DOJ charged with IP crimes from fiscal year 2001 and through 2006, 373 were imprisoned.

Despite the general increases in IP enforcement activity, agencies have taken little initiative to improve their data or evaluate their enforcement activity in ways that would enable them to identify and track certain trends or enforcement outcomes. For example, despite the importance agencies assign to targeting IP crimes that affect public health and safety, we were surprised to learn that most of these agencies lacked data to track their efforts in this area. Naturally, this is not true for FDA—by virtue of its mission, all its IP-related investigations affect public health and safety. Collecting better data, analyzing them, and reporting on progress toward goals could help make the IP enforcement agencies more accountable to the public and Congress, particularly regarding public health and safety. To address these issues, we made a number of recommendations to the IP enforcement agencies to improve analysis and reporting on their enforcement activities. In response, DOJ has said that it will take steps to routinely and systematically analyze IP enforcement statistics within fiscal year 2008. It also has directed the U.S. Attorneys Offices and the FBI to collect information on investigations and prosecutions related to IP crimes that affect public health and safety. DHS

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and HHS also generally agreed with these recommendations but have not yet indicated the specific steps they will take in response.

The need for improved coordination of federal law enforcement efforts has long been recognized. Around the same time Congress created NIPLECC, the executive branch created the National Intellectual Property Rights Coordination Center to improve federal IP enforcement and coordinate investigative efforts between ICE and FBI, but the center has not achieved its mission, and staff levels have declined. The center, which began operations in 2000, was set up to be a hub for the collection, analysis, and dissemination to investigative agencies of IP-related complaints from the private sector. However, the envisioned flow of private sector complaint information never materialized, agencies never reached agreement on their roles and responsibilities, and the center has gradually shifted its focus from investigative coordination to private sector outreach. We recommended that the responsible agencies reassess the mission of the center and communicate with the Congress regarding its purpose and required resources. In response, DHS indicated it concurred with this recommendation, and DOJ said it has directed FBI to coordinate with ICE to address this recommendation.

Concluding Observations

Mr. Chairman, we appreciate the opportunity to summarize our work on federal IP enforcement efforts. The challenges of IP piracy are enormous and will require the sustained and coordinated efforts of U.S. agencies, their foreign counterparts, and industry representatives to be successful. As the title of the hearing suggests, the issue of IP protection is not only important for U.S. producers, but also for the health and safety of U.S. consumers.

Our key findings show that the current coordinating structure comprised of NIPLECC and STOP has weaknesses related to leadership, permanence, and accountability. They also show that improved data collection, analysis, and reporting among the key enforcement agencies could help them better manage resources and performance and improve their accountability to Congress and affected parties. These findings were particularly important concerning IP crimes related to public health and safety, given that most agencies lack data to analyze or demonstrate the effect of their efforts in this area. The affected agencies generally agreed with our recommendations and some have begun taking steps in response.

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A number of legislative proposals are before Congress that would modify the federal IP enforcement structure.[2] As the committee continues to consider this issue and these proposals, we would be happy to provide additional information on where we believe the proposals address the weaknesses that our work has identified.

Mr. Chairman, this concludes my prepared remarks. I would be happy to address any questions that you or the other members of the Committee may have.

If you have any questions on matters discussed in this testimony, please contact Loren Yager at (202) 512-4347 or by email at YagerL@gao.gov. Other key contributors to this testimony include Adam Cowles (Assistant Director), Shirley Brothwell, Nina Pfeiffer, Jason Bair, and Adrienne Spahr.

[2]Intellectual Property Rights Enforcement Act, S.522, 110th Congress; Prioritizing Resources and Organization for Intellectual Property Act, H.R. 4279, 110th Congress.

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Related GAO Products

Intellectual Property: Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts. GAO-08-157. Washington, D.C.: March 11, 2008.

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