

Testimony of Jeff Kindler
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Before the Senate Finance Committee on
International Enforcement of Intellectual Property Rights
And American Competitiveness
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Thank you, Chairman Baucus, Senator Grassley, and the entire Finance Committee for inviting me here today.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Today's hearing focuses on competitiveness.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This is the incentive this American tradition has produced.

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

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

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

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

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

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

We must be vigilant.

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

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

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

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

Let's take them one by one.

COUNTERFEITING

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

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

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

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

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

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

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

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

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

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

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

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

PATENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REWARDING INNOVATION OUTSIDE THE UNITED STATES

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

That's obviously good for Pfizer.

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

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

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

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

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

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

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

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

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

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

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

OPTIONS FOR CONGRESS.

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

Let me offer a few suggestions:

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

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

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

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

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

CONCLUSION

A final point:

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

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

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

For the threat to IP around the world is real.

We need to fight for it in our trade agreements.

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

We need to fight for it in our diplomatic efforts.

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

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

Thank you.