

PERSPECTIVES ON PATENTS

HEARING

BEFORE THE
SUBCOMMITTEE ON INTELLECTUAL PROPERTY
OF THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
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MONDAY, APRIL 25, 2005

UNITED STATES SENATE,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 1:37 p.m., in Room SD-226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the Subcommittee, presiding.

Present: Senators Hatch, Cornyn, Leahy and Feinstein.

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

Chairman HATCH. Good afternoon. Today, I am pleased to chair the first hearing of the newly created Intellectual Property Subcommittee of the Senate Judiciary Committee. I commend Senator Specter for his support in establishing the IP Subcommittee. I also want to thank Senator Leahy for agreeing to serve as the ranking Democratic member on this important Subcommittee.

We have always worked together in a bipartisan fashion on intellectual property issues, and many others as well. For example, Senator Leahy and I, along with all Judiciary Committee members, joined together on legislation last year designed to curtail the diversion of patent fees from PTO. I have every hope and expectation that this Subcommittee will attempt to continue to address IP issues on a bipartisan basis.

To Senators Cornyn and Feinstein, I am grateful for all their work last Congress and appreciate the work that they do especially in securing passage of an important bill that passed the House last Tuesday, S. 167, the Family Entertainment and Copyright Act of 2005. I am pleased that this important piece of intellectual property legislation has finally been sent to the President.

That bill contains several provisions, including the anticensorship protections that Senators Cornyn and Feinstein championed in the Senate. The bill also authorizes the National Film Preservation Board, a matter of great interest to Senator Leahy, myself and many others.

Additionally, the bill contains a provision protecting certain technologies that help parents shield their families from material in motion pictures that may be too graphic for young family members. This has been a matter of some interest in my home State of Utah and I am pleased that it has finally passed both Houses of Congress. I commend Chairman Lamar Smith and Jim Sensenbrenner

and ranking Democratic members Howard Berman and John Conyers for their contributions in bringing this bill through the House.

Today, we will move to the patent side of the intellectual property arena. This is the first in a series of hearings that we plan to hold on patent reform to discuss in a fairly comprehensive manner some of the proposed changes to the substantive procedural and administrative aspects of the system that governs how entities here in the United States apply for, receive, and eventually make use of patents covering everything from computer chips to pharmaceuticals, to medical devices, to, I am told, at least one variety of crustless peanut and jelly sandwiches.

As the Founding Fathers made clear in Article I, Section 8, of the Constitution, Congress is charged with promoting the progress of science and useful arts by securing, for limited times to authors and inventors, the exclusive right to their respective writings and discoveries. It is my hope that today's hearing will help further that charge by encouraging an active debate on patent reform.

There is a growing consensus among those who use the patent system that reform is needed. For example, at least two of the organizations represented here today—the Business Software Alliance and the American Intellectual Property Law Association—have taken the initiative to develop discussion drafts of patent legislation, many key provisions of which have been incorporated in Chairman Smith's committee print over in the House.

I have also received a number of other suggestions, some of them fairly broad, some very narrow, from a variety of individuals and businesses around the country on changes they would like to see made to the current patent system. Both Senator Leahy and I always welcome constructive suggestions throughout the legislative process.

There appears to be a high degree of agreement on some issues relating to patent reform, such as the advisability of creating a new post-grant review process. There are other areas such as modifying the role of injunctive relief in patent litigation where, at least based on the testimony before us, significant differences remain. I hope that today's hearing will help to further the important debate regarding patent reform.

Now, in order to better understand the current state of affairs of U.S. patents and the climate from which these reform proposals have emerged, we will first hear from Jon Dudas, Under Secretary for Intellectual Property and Director of the United States Patent and Trademark Office.

We certainly welcome you, Under Secretary Dudas, back to this hearing room and look forward to hearing your testimony.

Under Secretary Dudas will help describe the growing importance of patent protection in the increasingly interdependent global economy.

The United States has consistently led the world in many critical areas of technology development, such as the computer hardware and software, telecommunications and biotechnology industries. To remain in the forefront of developing and translating new ideas into tangible goods and services for the benefit of Americans and other consumers around the world, there must be in place an equi-

table and efficient patent review and protection system both here and abroad.

We should all take pride in the fact that the United States Patent and Trademark Office is widely recognized as one of the leading IP organizations in the world today. Thousands of dedicated professionals at PTO are responsible for this success, but the agency faces great challenges in accommodating the ever-increasing number and complexity of patent applications being filed each year. As Under Secretary Dudas will detail, U.S. patent applications have doubled since 1992, and last year the PTO issued more patents, some 173,000 patents, than it did during the first 40 years of the agency's existence.

We will also hear today where PTO stands in the implementation of its 21st Century Strategic Plan. In addition, we will have an opportunity to discuss how PTO is responding to the key recommendations contained in the September 2004 Department of Commerce Inspector General's report entitled "USPTO Should Reassess How Examiner Goals, Performance Appraisal Plans and the Awards System Stimulate and Reward Examiner Production."

As well, we plan to explore the degree to which Under Secretary Dudas agrees or disagrees with the recommendations made by the National Research Council of the National Academy of Sciences in its major study, "A Patent System for the 21st Century."

We are pleased to have the distinguished Co-Chairs of this report on our second panel today—Dr. Mark Myers, of the Wharton School of the University of Pennsylvania, and Dr. Richard Levin, President of Yale University. We welcome them to the Subcommittee, as well.

On our third panel we will have a collection of inventors and protectors of intellectual property. This panel includes two inventors—William Parker, of Waitsfield, Vermont, and Dean Kamen, who was recently inducted into the National Inventors Hall of Fame. I am pleased to have these two independent inventors before us today because it helps to emphasize that although we lawyers have a modest role to play, the real purpose of intellectual property is to help ensure that the interests of innovators and consumers are both well served.

We will also hear from David Simon, Chief Patent Counsel of Intel, and Bob Armitage, General Patent Counsel of Eli Lilly. Bob is a veteran of testifying before the Judiciary Committee due to his work on improving the Schumer-McCain amendments to the Hatch-Waxman Act that were part of the 2003 modernization bill.

We are also particularly pleased to have with us Joel Poppen, Deputy General Counsel of Micron Technology. While Micron is based in Boise, I understand that they have some outstanding employees and facilities in Utah. Of course, I understand that. I have been there.

[Laughter.]

Chairman HATCH. I have enjoyed working with Micron on a number of trade issues to ensure that U.S. computer chip makers are treated fairly in Asia and around the world.

Last, and by no means least, we have Mike Kirk, Executive Director of the American Intellectual Property Law Association. Dat-

ing back to his days at PTO, Mike has long been a calm, clear and reasonable voice in all intellectual property legislation.

I would also like to recognize that there are a number of distinguished authorities on patent law present today that we were not able to invite to testify today. Particularly, I would like to note the presence of Herb Walmsley, of the Intellectual Property Owners Association, as well as representatives from a variety of intellectual property groups here in Washington.

It is my hope that today's hearing will help the members of this Committee better understand what works well and what should be improved in our current patent system. Before we attempt to fashion any legislative fixes to the patent system, it is essential that we carefully identify the problems we are attempting to solve.

We have learned time and time again—the Digital Millennium Copyright Act and the American Inventors Protection Act come to mind—that it can take a lot of time-consuming and hard work to forge successful consensus on IP legislation. I stand ready to roll up my sleeves and work with my colleagues in the Congress and other affected parties on intellectual property issues.

One area where I hope we can join together on a broad bipartisan basis is working to help curtail international piracy of U.S. intellectual property. We must be vigilant in our trade negotiations to make sure that our trading partners do not merely talk the talk. They must walk the walk on enforcing intellectual property laws.

Not to put too fine a point on it, many of us in Congress are watching USTR closely to see what the agency will do in relation to IP theft in the next special 301 round with respect to such countries as China and Russia. While there may—I emphasize the word “may”—be a case to support Russia's entry into the WTO, Russia should not be permitted to become the new China when it comes to only half-heartedly enforcing laws that some experts believe are only half-baked to begin with intended to protect against the piracy of intellectual property. The Subcommittee plans to hold a hearing on piracy of intellectual property in the week following the next recess.

Let me close by saying that I think the fact that 13 of the very busy 18 members of the full Judiciary Committee have made it a priority in their already overcrowded schedules to join this new Subcommittee speaks volumes about how important we on both sides of the aisle view intellectual property matters to the continued success and growth of the American economy and, of course, the quality of life of U.S. citizens and people all over the world.

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

So I look forward to today's hearing and the future work of this new Subcommittee, and I will turn to the Vice Chairman of this Subcommittee, Senator Leahy.

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

Senator LEAHY. Thank you, Mr. Chairman. I applaud you for holding this hearing. Today, the Intellectual Property Subcommittee does begin its public examination of all the issues—and there are a lot of them—facing the patent system.

We can sit here and enjoy the fact that the spirit of American innovation has made the United States the world's leader in intellectual property—something we would like to maintain throughout my children's and grandchildren's lives. But the expressions of American innovation in the patented goods and processes are only as good as the system that fosters and protects such innovation.

I share the growing concern about our patent system's ability to address many of the challenges it faces. I looked forward to hearing from Mr. Dudas at a hearing last Thursday, but that hearing was canceled at the last minute. I am grateful that you were able to rearrange your schedule to be here with us this afternoon.

We have all worked with Mr. Dudas, first, to get him confirmed, and that was a bipartisan effort. Both Republicans and Democrats on this Committee worked on it. Before, of course, we worked with him when he staffed the Republican leadership in the House and on their Judiciary Committee. I am looking forward to continuing our collaboration. You have a very exciting time ahead of you—exciting and probably daunting as we come into the 21st century.

I am also pleased that Professor Richard Levin of Yale University is here, and Professor Mark Myers from the Wharton School of Business. They are the authors of the acclaimed National Academy of Sciences report on patent reform. Their continued assistance is going to be very useful.

The size of the project we are undertaking seems to be reflected by the number of witnesses we have here, and I want to thank them all because they are the people who live with this every single day.

If I might, Mr. Chairman, I would like to draw attention to one of those witnesses, for it is particularly fitting that in discussing creativity and innovation, we have someone who knows and understands both and just happens to be a Vermonter. I want to thank Bill Parker for traveling to Washington today to share his thoughts with us as an inventor and a spokesperson for inventors.

Of course, he is part of our wonderful tradition in our little State, exemplified by the fact that the first U.S. patent issued and signed by George Washington went to a Vermonter. I just thought I would throw that in, and we have been doing it ever since. I think in at least one year, on a per-capita basis we had the most patents in the country.

In 2002, the House and Senate directed the Patent and Trademark Office to develop a five-year plan designed to modernize and expedite, and parts of that plan are being implemented. Last year, I supported a compromise in the Appropriations Committee that will, for one year, prevent PTO user fees from being diverted to other Government programs. So I am interested in hearing more from our witnesses about the implementation of the PTO's plan. I am also interested in discussing the proposal we have all been hearing that suggests improvements in the quality of the patents the PTO is issuing.

You have a herculean task. The volume of patent applications has increased three-fold since the 1980s. Just to put this in perspective, the PTO receives more than 350,000 patent applications every year. They approved 187,000 in 2004 alone. That is roughly

500 approved patents every single day. I think that could be a matter of concern.

When you have non-innovative inventions that are patented, some patent-holders fear they will spend more time litigating than they do innovating as a result of predatory tactics. It is a real problem. We should explore ways to alter the patent examination process in order to allow for patent challenges before you tie it all up just with costs of litigation. I am especially interested in the suggestion that we find ways to allow outsiders with prior art to present information in the examination stage.

At the same time, we are hearing calls to reform the very way in which these cases are being litigated. One criticism I have heard is that the standards which courts use to determine whether a patent violation is willful have been applied in a way that encourages patent-holders to wear blinders to what others invent.

We have also heard about abusive litigation practices of “patent trolls,” described to me as companies that neither invent new or produce anything at all, but simply acquire patent rights and then push the bounds of their patent, suing patent-holders who actually do innovate. I am interested in hearing more about these concerns, as well as proposed solutions. I want to encourage those people who actually do innovate, and they ought to be able to get the benefit of their innovation. I don’t want somebody who is just going to leach on their innovations.

So these are just a few of the things we have before us. I can think of no better issue to start off with. The House finally granted final passage of the Family Entertainment and Copyright Act. I know looking around this table, Senator Hatch, Senator Cornyn, Senator Feinstein and myself sponsored that. We approved it last year and again this year, in February of this year. Chairman Hatch and I worked cooperatively on that legislative package last year, with the result that it has now been enacted by the Congress. It is an example, as the Chairman was saying, of bipartisan legislation.

I have more which I will put in the record because I find with the beauty of spring and pollen, my voice is gone. Thank you, Mr. Chairman.

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

Chairman HATCH. Thank you, Senator.

Senator Cornyn, would you care to make any comment? Then I will call on Senator Feinstein, since this is our first meeting.

**STATEMENT OF HON. JOHN CORNYN, A U.S. SENATOR FROM
THE STATE OF TEXAS**

Senator CORNYN. Mr. Chairman, I don’t have anything extended, but I did want to congratulate you as the new Chairman of this brand new Subcommittee for convening this hearing and the series of hearings on patent reform.

Of course, as Senator Leahy said, intellectual property protection has been something that the Judiciary Committee has been concerned about. Senator Feinstein and I, along with Senator Leahy and you, had a chance to work on some important legislation that has just recently passed to do that.

It is important for America to maintain our edge as the innovator in the world in a global economy that we do provide a means by which innovation can be fostered, but also, once people invest their intellectual capital and their hard-earned money into a product, that it be protected. This is a matter that remains a tremendous challenge around the world.

I am delighted to be on the Subcommittee with you. Unfortunately, I won't be able to stay long because I am going to be working on another subject near and dear to your heart, Mr. Chairman, and that is asbestos. But I do want to congratulate you for holding the hearing, and thanks to all of our witnesses for contributing their insight and expertise in tackling some of the tremendous challenges we have before us.

Thank you.

Chairman HATCH. Thank you, Senator.

Senator Feinstein, and then we will go the witnesses.

**STATEMENT OF HON. DIANNE FEINSTEIN, A U.S. SENATOR
FROM THE STATE OF CALIFORNIA**

Senator FEINSTEIN. Thanks very much, Mr. Chairman. I would like to echo those words. Patent and copyright protection is a very big deal to California, and that is really why I am here.

It is interesting to harken back on an early patent, and that was a patent which was issued to Levi Strauss for jeans in 1873. I believe at that time, it was a 17-year patent. It is now a 20-year patent from date of application, or 17 years. So there are a lot of questions about these patents. Is 17 years fair? Should it have been longer?

I mean, when Levi Strauss came forward in those early Gold Rush days, it was a very big deal to come up with a fabric like jean fabric because the pants of the miners were wearing out too fast. Yet, as soon as that patent expires, you see Levi-type jeans everywhere. In this day of high costs, high labor costs, high every kind of cost, I have begun to wonder whether the time for the patent is really an adequate time.

So I look forward very much to hearing your comments, Mr. Dudas, on that subject.

May I put my full remarks in the record, please?

Chairman HATCH. You certainly can.

Senator FEINSTEIN. Thank you very much, Mr. Chairman.

Chairman HATCH. I appreciate that, Senator Feinstein.

We will turn to you, Mr. Dudas. We are honored to have you here and we appreciate the work you are doing in the Patent Office, among other things.

**STATEMENT OF JON W. DUDAS, UNDER SECRETARY OF COM-
MERCE FOR INTELLECTUAL PROPERTY, AND DIRECTOR,
U.S. PATENT AND TRADEMARK OFFICE, DEPARTMENT OF
COMMERCE, WASHINGTON, D.C.**

Mr. DUDAS. Thank you, Mr. Chairman. Thank you, Ranking Member Leahy and members of the Subcommittee. It is an honor for me to testify here today at the first hearing of this Subcommittee.

I would like to note that it is an appropriate time to reflect on the incredible success of innovation and of our patent system in the United States. It was 215 years ago this month that our young Nation adopted our first patent statute. There is a lot of talk about history. It was 215 years ago this month, on April 5, 1790, that your predecessors in the Senate passed the final version of the statute and President George Washington signed it into law on April 10.

The benefits of our patent system have always been obvious to Americans. You are all familiar with Article I, section 8, clause 8 of the Constitution granting Congress the power “to promote the progress of science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

James Madison wrote in one of the Federalist Papers, “The utility of this power will scarcely be questioned.” He was right. That clause was adopted into the Constitution without a single dissenting vote. It was adopted without even any recorded debate.

History has repeatedly affirmed the wisdom of these decisions of our Nation’s Founders. The tremendous ingenuity of American inventors, coupled with an intellectual property system that encourages and rewards innovation, has propelled the growth of our Nation from a small agrarian society to the world’s preeminent technological and economic superpower.

The flexibility and strength of our system have helped entire industries to flourish rather than perish. Everyone has benefitted from the innovative products encouraged by that system. And all of this technology finds its way into the public domain within 20 years, freely available to any and all, going to your thought, Senator Feinstein.

The success of this system has not been limited to the United States. It has been the basis for economic development in nations throughout the world. Unfortunately, a growing chorus of critics is questioning whether the fundamental patent system that has been so critical to the growth of innovation and economic success in the United States and other nations will enhance or hinder the development in their own nations.

Many of the nations questioning the efficacy of this intellectual property system have become hotbeds for the manufacture and export of counterfeit goods, with more than 90 percent of goods in some industries being counterfeited and pirated. Quite frankly, in many cases that thought process occurs in reverse. Many nations that have expanded economic development by allowing their citizens to counterfeit and pirate others’ intellectual property have then come to question a system that encourages and rewards innovation and discourages copying and free-riding.

I believe it is our responsibility not only to do everything we can to perfect the patent system in the United States—something you are clearly doing by holding this hearing today—but we must also actively educate the rest of the world that it is fundamentally the right system.

Having the fundamentally right system, however, is not enough. I will be the first to acknowledge that even the best system in the world can and should improve. As you know, the genesis of the

USPTO's 21st Century Strategic Plan was the result of directives from the President and the Congress that the USPTO improve. We are implementing a multitude of improvements and are building on these initiatives, and there is more that we plan to do.

To remain the best patent examination system in the world, the USPTO is focused on improved quality and productivity. To ensure the timely granting of patent rights, we must reduce our backlog of patent applications. Earlier this year, the USPTO announced several initiatives to improve quality and efficiency. They include increasing our transparency, improved our ex parte reexamination, and saving applicants tens of millions of dollars by revamping our process of appeal brief submissions.

The USPTO is a collection of 7,000 people, including scientists, engineers and Ph.D.s, many of whom spend their time considering how we might improve our system. A multitude of others are reflecting upon our system as well, and many of them have been or will be at your doorsteps to suggest changes.

We are hearing legislative proposals in three general categories—operational issues and administrative issues, litigation reform, and convergence of international laws and best practices. In my view, each of these discussions must center on how the patent system encourages innovation and how well it serves the public at large.

We and you, I believe, must look at these issues from every angle. We must look at them from the perspective of the independent inventor who may be the next Thomas Edison, to the perspective of a large and successful company that believes its innovations are being tied frivolously in unnecessary legal knots. We must look at these proposals from the perspective of an economic superpower negotiating treaties to create a better intellectual property system throughout the world, to the perspective of an American patent examiner who is striving to improve high-quality and timely examinations.

I will certainly not shy away from focusing on how we can improve our processes at the USPTO. We have spent the last three years working to do just that, and I am thankful for all of the work you have done on this Committee in passing legislation that will give us many of the tools that we need to improve. And there is definitely more that we can do.

Although Washington is a place where it is easy to identify problems and give excuses, it is my responsibility to identify opportunities and deliver results. I fully appreciate that you will hold the USPTO and me accountable, and I am confident that we will deliver you results.

As you reflect upon the proposals you will hear, I urge that you not focus exclusively on litigation—an occurrence at the end of the process—nor exclusively on how the USPTO handles an application—the middle of the process. Those are areas that must be reviewed, and must be reviewed vigorously, but patent quality begins with the application and it begins with the applicant.

When we have shown the light on the USPTO, we have found areas where we can improve and we will continue to implement those improvements. But I can tell you that the challenge I hear most often from our examiners in the office is the problem quality.

I do not purport to have all of the answers at this time. However, I can assure you that we are reviewing this issue within the USPTO and will welcome the opportunity to share what we learn with you and how we believe we can appropriately address the issue of application quality.

Let me assure you we are committed to adopting practices and policies at the USPTO that promote the innovation and dissemination of new technologies. While we work to improve our systems by internal reform at the USPTO, we realize that measures within your domain will make invaluable contributions to our system. In this regard, the USPTO and the entire administration look forward to continuing to work with you as you consider legislation to ensure that the U.S. patent continues to lead the world.

Thank you.

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

Chairman HATCH. Thank you, Mr. Dudas.

Now, there appears to be a growing consensus that the U.S. should abandon its long-held policy which rewards the first to invent in favor of the international system of first inventor to file. For example, the NAS report is supportive of this concept.

I understand that former Commissioner Mossinghoff and colleagues have produced empirical evidence that our existing system actually works to the detriment of small independent inventors. I also understand that under this new system, you can't just be the first to the PTO; you must still be a genuine inventor, not necessarily the first inventor. Nevertheless, it may be counterintuitive to some that the "first to invent" policy should be discarded, since it is based on the principle "first in time, first in right."

I would like to know what the administration's position is on this particular issue. If there is no final position at this time, please take the opportunity to explain to the Subcommittee and the public what this issue is all about and what the tradeoffs really are.

Mr. DUDAS. Absolutely. Thank you, Mr. Chairman. Well, there is growing, broad support among private sector groups and internationally moving toward adoption of a first inventor to file standard. It is perceived of by offices throughout the world as an international best practice.

As you point out, advocates point to the fact that it is a simpler method. There are downsides to our current interference practice which make it very difficult to enter into the subjective elements of finding out who was the first to invent, the kinds of questions you need to ask there.

I believe that "first to invent"—many believe that it is philosophically more consistent with the basis of our patent system. Senator Feinstein brought up that the basis of our patent system is to disclose. Ultimately, it is to disclose innovation; it is to make things available. If you choose to use the patent, you choose to invent and protect, and that is a way to incentivize you to invent because you get that protection. You can also go the trade secret route, where you will hide what you have. You will keep secret what you have, but you don't have the protection of the law. What our system should do is encourage people to disclose.

Supporters of our “first to invent” system have focused on concerns that others can more easily steal inventions and that applications might be filed more rapidly. So a small inventor or a new inventor might feel more pressure to apply quickly and then question whether or not there is the quality. So there is a tradeoff in that regard.

I am eager to hear the debate on both sides. It is a debate that has been around for many decades. But, again, the studies you point to by former Commissioner Mossinghoff have suggested and have shown that the high costs of our current interference practices under our “first to invent” system may be disproportionately falling on independent inventors and small businesses.

Chairman HATCH. Your testimony and the testimony of many others here today supports the development of a new system of post-grant review at PTO. Can you tell us where this issue is among your priorities for patent code reform, how much you believe it will cost and whether you have any position on the issue of whether the challenge period should last for nine months, two years or some other time period?

Mr. DUDAS. It is a high priority. It is a very high priority, but a post-grant opposition proceeding is something that the United States Patent and Trademark Office has talked about from the very beginning of our strategic plan back in 2002 when we began putting that together.

Some of the questions you ask depend on how that post-grant opposition system might work. I believe that we can implement that system in the United States Patent and Trademark Office. I think the post-grant opposition system is an answer to many of the problems that people raise right now.

One of the concerns now is that litigation is too costly, litigation takes too long, litigation is too subjective, and perhaps you are not sitting before the experts when you go to a district court. Post-grant reexamination is a proceeding we have in the office right now that allows you to go before the office, but doesn’t give you all of the freedoms; it doesn’t give you all of the options that you have in litigation. Post-grant opposition gives you the benefits of the protections of litigation, while still gets you before the office.

I think we can implement that, and it will take resources and it will be necessary for us to get the resources in place. It will be something that, if it is authorized, we will have to have the appropriation for it as well.

As far as the time period, I think there is a lot of agreement toward a nine-month. At the Patent and Trademark Office, we believe that it should be a one-year period where you can raise an issue in post-grant opposition, and then after that time if you show a credible sign of being sued for infringement or have otherwise a reason to bring that up.

Chairman HATCH. Well, let me just ask one last question. Let me draw you into the thicket of injunctive relief. I know that there is no final administration policy on either the BSA or the AIPLA versions of the injunction provision. Mr. Kamen, who will testify later, also has strong feelings about this issue, coming from the small inventor perspective.

I am not asking you for a final answer on this issue at this point because I think the affected parties need to continue to work on this issue, but help us understand the issues involved.

Please tell us what is at stake and why the tech folks and biotech folks, as well as some small inventors, look on this issue so differently, and please help us define the problems associated with the granting of injunctions with respect to patent litigation.

Mr. DUDAS. Thank you.

Chairman HATCH. My time is up, so if you could answer this.

Mr. DUDAS. I am sorry. I didn't hear the last—

Chairman HATCH. My time is up, if you could answer this.

Mr. DUDAS. Okay, absolutely. Thank you. This is an excellent example of where a balance needs to come in, and you made a point in there that you need to listen to everyone. In my testimony, I pointed out that on these kinds of issues we need to listen to independent inventors, we need to listen to big companies, we need to listen across industries. I think you are right to say that we need to hear a whole lot more.

I will tell you one thing that I find disturbing. A study was done last year that talks about increases in litigation costs. The increases in prosecuting patents went up 1 percent. The increase in litigation across the board went up 1 percent. The increase in patent litigation and intellectual property litigation went up 32 percent.

So there is statistical evidence and there is also anecdotal evidence that some predatory practices in litigation are finding their way into intellectual property, into the courts, and we are seeing more issues along those lines. I think it is important that we look at that.

The other side of the issue which you hear from many people—and this is what is very important—is there is a real problem, but is the injunctive relief solution the right solution, is what people are raising. It is throwing the baby out with the bath water?

Injunctive relief has been looked at because the right is an exclusive right, the right to exclude others from the use of your patent. Under injunctive relief, there are four areas where you need to look to determine whether or not there is injunctive relief. One area is whether or not there is irreparable harm. I think the debate really turns on that.

If you hold a patent and you have a right to exclude others, then if you can't get injunctive relief, is there or is there not irreparable harm? The moment you allow someone to encroach upon that or develop along those lines, the original patent owner loses the right to exclude.

If you compared it to a real property example, if someone holds a deed and title to property and someone else came along and said I would like to build on that property, I don't think you own it, et cetera, does the court say, well, you can build so long as you can get monetary damages? That is what I think the debate has turned on.

I think you hear other industries being concerned because they want to maintain that they have consistently the right to exclude. They are worried that this would create a system of compulsory licenses, but you see a real difference based on the experiences that

different industries have had both in the courts and in the patent system.

Chairman HATCH. Thank you.

Senator Leahy, we will turn to you.

Senator LEAHY. I raised earlier this question of patent-holders seeking multiple continuations of their patents, and I understand the practice may be abused. One, I would like to know if you feel there is a possibility of it being abused, and would it be a good idea to put a specific numerical cap on the number of times a patent applicant can file an application for continuation, three strikes and you are out or something like that?

Mr. DUDAS. I am glad you raised that point. Continuation practice is something that we are looking at in our office both in terms of quality and in pendency, because over 25 percent of the work we are doing is working on continuing applications. There are many legitimate reasons to have continuing applications, but in essence that means a quarter of our work is going to rework.

Our system allows a great deal of flexibility, but I think we are at a point now—and it is something that many of you have raised—where we have to start choosing how many different flexibilities we can have and what judgments we need to make in our system. There are cost/benefit analyses that perhaps didn't exist that do exist today after we have broken records in the number of applications we receive.

Senator LEAHY. Are you seeing an abuse of this continuation?

Mr. DUDAS. There are certainly people that are reporting that there are abuses of the continuation practice. Particularly, I think what people are focusing on is the idea that you can broaden out your claims through a continuation after another technology develops. So we have certainly heard reported abuses and there is evidence that people have tried to use continuation practice in that light.

I will also tell you from our standpoint I don't know if a hard limit is the right answer. We have looked at that in our office and there are concerns if there can be more. But what we ask our patent applicants to bring up—this is one of the questions at the heart of application quality that I referred to earlier. Perhaps we need to either charge more or we need to have them have higher burdens to bring in if they are going to have that many continuations.

Senator LEAHY. Well, you mention charges. One proposal I have heard to help small inventors is the elimination of filing fees at the PTO for individual inventors and small businesses. For large businesses, you would have to have some kind of a standard, of course, that they would be required to pay. I wonder if you have a position on that proposal. What about universities, some of whom partner with the private sector? Should they part of an exemption from fees?

Mr. DUDAS. I am glad you raised that. I think there are concerns with a system that would allow no cost/benefit in whether or not to file a patent application. Currently, under our system small inventors, universities, independent inventors and small businesses, as defined by the Small Business Act, get half off of fees. So there is a sense that there is a break in place. There are those who ques-

tion whether or not there are too many applications that get a price break, a half off.

There is a concern sometimes in our system, often in other patent offices, of whether or not junk is filed, whether or not the system allows for too much to come in and that bogs down the system. If there were no fees whatsoever for an application for any particular group, I think that is a concern that we would have to look at, if there was no cost/benefit that was made at all. We want to make certain of the quality of applications that come in. Our office and the administration has always been supportive of having smaller fees for smaller inventors and independent inventors.

Senator LEAHY. I think we should, but you talk about the high number coming in. I have heard that the patent examination process doesn't allow for relevant information of third parties to be brought to the PTO prior to the time when you are in litigation. I am wondering if there should be a better way of getting information from third parties, those who work in the same field and have expertise and have an incentive to make sure the new inventions are truly innovative, some kind of a partnership there.

Might that be a way to help the PTO so that you are not over-patenting inventions? You have some reference in your testimony to something along this line. Would you want to elaborate on that, please?

Mr. DUDAS. Certainly, that can be helpful. In fact, we are engaged now with partnerships with a number of different industries, not on particular patent applications, but our examiners will get together with industry representatives and discuss what relevant art is, what is the state of art in each of the industries.

This is particularly important when you begin to see patenting techniques used in new industries. So in the financial industries, after the Supreme Court decided *State Street Bank*, we saw patenting techniques used more and more in certain industries. Our examiners, who are always eager—and when compared internationally, the examiners throughout are always eager to get more information and are working with sometimes hundreds of people from the industry coming in and training our examiners, et cetera.

I think what you are talking about is a more robust system of seeing applications, published applications, et cetera, and being able to submit prior art with a little bit more relevance. We are very open to that. We would have to manage it properly.

Senator LEAHY. I will put my other questions in the record, but I was concerned about a letter I received from the head of the Patent Office Professional Association. You probably have seen it. They claim that the recent contract proposal has demoralized a workforce that they feel is highly motivated. It says PTO wants to reduce current performance incentives and eliminate a current contract provision that says employees will be treated equitably and fairly by management. According to their newsletter, they say when the PTO's automated systems fail to function, as sometimes they will, employees will be sent home without pay.

Now, in the 21st Century Strategic Plan you speak of how you get a highly motivated workforce. Is this showing an area where that motivation may be undercut?

Mr. DUDAS. I don't think ultimately it will and I sincerely hope it isn't. I can tell you one thing where our union, our examiners and management in our office agree. We are one team and our goal is to make sure that we provide the examiners with the tools they have.

I would hate to think—and I have talked to a number of folks—that a proposal would in any way cause a demoralization because it is a discussion process. I have solicited comments from our union, from our managers and from our examiners. In fact, I get some of the best comments on how we can change and how we can improve from working out in the fitness center in our office. So this is meant to be a collaborative process, one in which we are bringing everyone in.

We certainly feel a certain amount of responsibility in my office—I feel it—for us to be able to improve and become more efficient, and the only way we can do that is by passing those—within in the office, how can we improve? So my sense would be that there is not a sense of demoralization based upon that, or if there is, I think that will be remedied as people discover how there will be give-and-take and discussion as we go forward. The goal is indeed to give our examiners the tools they need. We are the most efficient office in the world and our examiners, I am certain, are the best in the world.

Senator LEAHY. Thank you very much. Thank you, Mr. Chairman.

Chairman HATCH. Well, thank you, Senator Leahy.

Senator Feinstein.

Senator FEINSTEIN. Thank you very much, Mr. Chairman.

Mr. Dudas, I want to ask you a question about university of patents. The University of California is listed by the Patent and Trademark Office as the university that received the largest number of patents in the Nation last year, with over 400 patents. Its patents and its licensees have contributed a lot to the development of high-tech and biotech in California. All of American biotech sprung right out of the University of California. It was amazing. However, in a university setting research is not always done with patenting in mind, and depending on how changes in the patent system are structured they may have an adverse effect on large research-oriented universities.

What do you think the impact of some of the reforms mentioned such as the change from the current "first to invent" standard to a "first to file" standard will be on universities?

Mr. DUDAS. I think you raise what is at the heart of what is happening within universities. There is a sense that university research and what professors want to do are sometimes inconsistent with the patent system. The patent system is about protecting and keeping private until you apply. The university system is often about getting information out as quickly as you can.

My sense is that the universities can do just as well in a "first to invent" as in a "first inventor to file" system. Particularly as you point out, I think the universities have really gotten beyond the issue, most universities have, through education, of wanting to publish before they think about patents.

You talk about an incredibly successful system in the University of California, Wisconsin, Stanford. There are a number of universities that now work that problem out very well. I think that universities can and will thrive in either environment. The Bayh-Dole Act is an example of how universities came into thrive where government couldn't thrive, where government couldn't really develop these patents. So the experiences I have had in working with universities and seeing that is that they adjust very rapidly and can thrive under either system.

Senator FEINSTEIN. But are you saying that they are better off under the "first to invent" rather than "the first to file?"

Mr. DUDAS. I am not saying that they would be better off under "first to invent," and I apologize. They probably would be better able to articulate, if they do feel that way, why they would feel that way. I find that the system is one that can adjust either way and I don't feel that a "first to invent" system—or at least it is not obvious to me why that would be a preferred method for universities.

Senator FEINSTEIN. Could you tell me a little bit more about the backlog in the patent office and what other steps you would take to ensure that the patent office would be able to handle the new class of proceedings on top of its existing workload?

Mr. DUDAS. Yes, two questions. One was about the backlog and the second is how we can handle the hiring that we are doing now.

Senator FEINSTEIN. The number in the backlog.

Mr. DUDAS. The number in the backlog, absolutely. In the last 20 years, the Patent and Trademark Office has broken a record every single year for more than 20 years in how many applications it has received. That is great news for our economy. It is great news for the United States because, of the American filers, that number has consistently gone up.

It is also great news for the USPTO, but it is a challenge as well. Despite the growing numbers of applications, certainly in the last several years and years before we did not hire in record numbers. We now have, because of the bill that was passed last year—I am sorry.

Senator FEINSTEIN. I guess I am asking you what is the current backlog.

Mr. DUDAS. The current backlog is approximately 490,000 applications in the backlog.

Senator FEINSTEIN. That is a big backlog.

Mr. DUDAS. That is a very big backlog.

Senator FEINSTEIN. Is that the highest ever?

Mr. DUDAS. It is the highest ever, and it won't comfort you much to know that it will certainly grow over the next few years.

Senator FEINSTEIN. So what are you doing to have at it, so to speak?

Mr. DUDAS. What we are doing now is we are hiring more examiners now. We are going to start getting at that backlog. The reason that backlog will grow is because pendency is measured going backward, basically. If pendency is at 28 months, that means we are measuring a patent that comes out today and 28 months ago it was filed.

So we know you could hire 12,000 patent examiners now and it wouldn't affect where it goes in the next two years.

What you will see is three years down the line, four years down the line, the hiring we are doing will have an effect. We are hiring at record numbers now more patent examiners than we have ever hired before. Eight hundred and sixty patent examiners is what we plan to hire this year. We have already achieved 80 percent of the goal.

Senator FEINSTEIN. How many do you have now?

Mr. DUDAS. We are going from 3,600 to about 4,400, and there will be some attrition in there. We are hiring a quarter of our workforce.

Senator FEINSTEIN. I guess the second part—well, I guess the hiring is the answer to the second part of the question.

Thank you very much, Mr. Chairman.

Chairman HATCH. Well, thank you, Senator.

Could I just ask you for some help? We would like you to continue to work with us as we fashion patent reform legislation. We would like to have the best advice you can give us.

Secondly, Senator Lieberman and I will likely be shortly reintroducing our bioterrorism legislation. This bill has several IP provisions in it and I just want to know if Senator Lieberman and I can count on you to aid us and help us with that on this very important bipartisan bill.

Mr. DUDAS. Absolutely. Whatever we can do we will do, and thank you very much for having me.

Chairman HATCH. Thank you so much. We appreciate you taking time, we appreciate you being here and we look forward to working with you on these issues and we appreciate the good work you do.

Mr. DUDAS. Thank you.

Chairman HATCH. Thanks so much.

Panel two will consist of Dr. Richard C. Levin, President of Yale University, from New Haven, Connecticut, and Co-Chair of the Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology and Economic Policy of the National Research Council, and Dr. Mark B. Myers, Visiting Executive Professor, Management Department, at the Wharton Business School at the University of Pennsylvania, in Philadelphia, Pennsylvania, and Co-Chair of the Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology, and Economic Policy, National Research Council.

We welcome both of you here today and look forward to hearing what you have to say. We will start with you, Dr. Levin, first, and then we will go to Dr. Myers.

STATEMENT OF RICHARD D. LEVIN, PRESIDENT, YALE UNIVERSITY, NEW HAVEN, CONNECTICUT, AND CO-CHAIR, COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY, BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY, NATIONAL RESEARCH COUNCIL

Mr. LEVIN. Chairman Hatch, Senator Leahy, Senator Feinstein, thank you for offering me the opportunity to discuss the National Research Council's recommendations for improving the patent system in the United States. Patents play a crucial role in promoting the technological innovation that is the most important underpin-

ning of economic growth. I am grateful to the Subcommittee on Intellectual Property for scheduling this hearing.

The project undertaken by the National Research Council was the most comprehensive review of the patent system in decades. Our committee was perhaps the first to bring together practicing patent lawyers, judges, academic lawyers and economists, business leaders, technologists and inventors.

We started with highly divergent views, but over the course of our deliberations our views converged and we reached consensus on several important recommendations. We concluded that, on the whole, the patent system is working well and does not need fundamental revision. Yet, we did note some causes for concern.

The sheer volume of patent applications, especially those involving new areas of technology, overwhelms the examination corps in ways that affect the quality and timeliness of decisions. In addition, it has become more expensive to acquire patents, to obtain licenses to patented technologies, and especially to enforce and challenge patents through litigation.

Our recommendations are set forth in greater detail in an accompanying written statement coauthored with Dr. Myers. But, here, I would like to emphasize three main themes.

First, we believe the Congress and the PTO should take steps to ensure the quality of patents that are issued. The single most important step would be the establishment of a simple administrative procedure for opposing a patent after it has been granted, a post-grant review system. The process should be timely and efficient so that uncertainty can be resolved quickly without either inhibiting socially productive investment by competitors in situations where the patent proves to be invalid or, on the other hand, encouraging wasteful investment when the patent proves to be valid.

A new post-grant review system is needed because the existing inter partes reexamination procedure only permits challenges to be lodged on narrow grounds. It is rarely used and has not proven to be effective. The only way to challenge patent through the courts today is to infringe it and to draw either an infringement suit or a demand to take a license. This is an unnecessarily expensive method to resolve doubts about a patent's validity, and disputes take many, many years to resolve.

Patent quality can also be improved by the assiduous application of the non-obviousness standard by the Patent and Trademark Office. The PTO needs to develop new approaches to gathering information about the state of the art in emerging areas of technology, relying on outside experts when patent examiners lack expertise.

The committee commends the PTO for the development of guidelines in emerging technology areas such as genomics and business methods. It is important to offer such guidance promptly as new technologies emerge. The committee also recommends that the Congress provide more resources for the PTO to hire needed examiners to improve its information systems and to fund a post-grant opposition procedure.

A second theme beyond that of patent validity is the harmonization of the United States patent system with the European and Japanese systems. Differences among the world's major patent regimes entails wasteful duplication of effort by both inventors and

governments. The committee believes that gains in efficiency from harmonization would be considerable.

The United States is now the only country that gives priority to the first person to reduce an invention to practice. Elsewhere, it is the first inventor to file who is given priority. The latter test is objective. What date did you file with the patent office? The former requires years of discovery, reams of depositions and hours of trial testimony. Moreover, the U.S. is the only country in the world that requires the patent-holder to prove that he or she has disclosed the best mode of practicing a patent. This, too, is costly and time-consuming to prove. Harmonization with global practice makes sense.

Finally, the committee recommended that the Congress mitigate other subjective elements in the law that contribute to the extraordinary expense of patent litigation. For example, Congress would be well advised to eliminate or modify the standards governing inequitable conduct. There should be penalties for misconduct by patent applicants, but misconduct should not automatically invalidate a patent.

Similarly, the doctrine of willful infringement should be modified because willfulness is subjective and costly to prove, and the doctrine creates a perverse incentive for inventors to avoid the study of prior art, lest they fail to cite a patent that turns out to be relevant.

In this brief overview, I have not mentioned all the recommendations of the committee which are explained more thoroughly in our written testimony and, of course, in our full report. My colleagues and I on the committee recognize that some of our proposals will engender controversy, but we believe that is imperative that the United States take the steps necessary to ensure the quality of patents, to harmonize patent systems and to reduce the cost of patent litigation.

I would be pleased to answer any questions. Thank you.

Chairman HATCH. Thank you so much.

Dr. Myers, we will take your testimony.

STATEMENT OF MARK B. MYERS, VISITING EXECUTIVE PROFESSOR, MANAGEMENT DEPARTMENT, WHARTON BUSINESS SCHOOL, UNIVERSITY OF PENNSYLVANIA, PHILADELPHIA, PENNSYLVANIA, AND CO-CHAIR, COMMITTEE ON INTELLECTUAL PROPERTY IN THE KNOWLEDGE-BASED ECONOMY, BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY, NATIONAL RESEARCH COUNCIL

Mr. MYERS. Chairman Hatch, Senator Leahy and Senator Feinstein, I join my colleague, President Levin, in thanking you for the opportunity to discuss the recommendations of the National Academy of Sciences concerning the patent system.

Rather than speak from my experience now at the university, I would like to speak from my experience of a career of 37 years that I spent in industrial research and development at both large and small entrepreneurial firms. In the last ten years of my career, I was head of Xerox's corporate research, where I was involved in the process of creation of intellectual property which offered key options for economic growth of the firm. In the creation of new firms,

patents were an imperative to attract the investment necessary to fuel early growth.

Over these many years of experience and practice, there were two very important innovative trends that really had major impact on the ability to establish a firm competitiveness. One is the ever-accelerating pace of innovation. Time frames once measured in decades are now measured in years, years are now measured in months, and months are measured in days. A second major trend has been the globalization of markets and technology sourcing. The innovation process is unconstrained in time, place and movement.

These trends place new requirements on our patent system. If it is going to continue to enable innovation, as it has so ably done in the past, the quality of patents and issues of potential infringement must be determined earlier in the innovation process. We need common standards of right to use of technology across global markets. Uncertainties with respect to these rights of use create negative incentives for innovation investment. The recommendations of this report speak directly to the needs of patent quality, earlier validity determination, as well as moving us along toward international harmonization.

I would like to join now President Levin and accept questions from the panel.

[The statement of Messrs. Levin and Myers appears as a submission for the record.]

Chairman HATCH. Thank you very much.

Dr. Levin, I am tempted to ask you a question on the minds of many parents, what role will the new essay on the SAT play in college admissions, but I won't ask you that.

Both of you come from leading academic institutions. The NAS report contains a lengthy discussion of the extent to which universities should be liable in patent infringement cases. I will stipulate that probably no party enjoys patent litigation, certainly not universities.

I am struck, however, by the examples that you gave on pages 74 to 76 of your report. This includes several extremely important university-assigned and licensed biotechnology inventions, such as the Harvard mouse and the University of Wisconsin stem cell lines. The Federal Circuit, in *Madley v. Duke*, distinguished between research, quote, "solely for amusement to satisfy idle curiosity or for the strictly philosophical inquiry is protected," but that "organized scientific research with commercial dimensions is not protected from infringement liability."

Given the manifest commercial character of some university-based science, why should this type of research be shielded? Your report notes that, quote, "University administrators and legal counsel were uncertain what precautions to take to avoid infringement."

Now, as members of the NAS study and key university leaders, can you update us on the developments in this area since the report was written and tell us the extent to which you believe that immunity should be granted to university research and why?

Mr. LEVIN. Well, the committee did not in the end recommend a blanket exemption for university research. We actually looked at the possibility of crafting several types of narrow research exemptions and actually noted strengths and weaknesses of each of them,

and in a sense tossed it back to you, Senator Hatch, and others in the Congress for resolution.

We are concerned about access to research tools, but we have worked out ways of doing it. I mean, I would say that there are increasing numbers of agreements these days within universities, even since our committee completed the substance of its work more than a year-and-a-half ago. We are getting better at figuring out how to license these tools and to make our faculty compliant with taking licenses for the intellectual property they are using. On the other hand, it is important that we not inhibit fundamental research that is undertaken for non-commercial purposes.

Much more is proprietary now in the area of research tools than was the case even a decade ago. So to do even fundamental research in universities now, especially in the genomics area, requires significant numbers of licenses and agreements to be crafted. And we are worried about this, but as I say, it is not easy to craft good language.

In principle, what you would like to do is protect basic research that has no commercial purpose. But, of course, universities are engaged in commercial activity and we shouldn't have an unfair advantage in competition, so we should have to take the same kind of licenses the private sector takes. So you see the dilemma. There is no simple answer to this.

Chairman HATCH. Dr. Myers.

Mr. MYERS. As a study group, we did not come to one mind on this question. Part of it is it is a very complicated issue which people from the university community and industrial community have not yet reached common ground, and so it is clearly going to be the subject of more conversation.

I think, though, it is an extraordinarily important question for the following reason. One of my focuses is on international competitiveness, and particularly competitiveness in U.S. industry. As we have seen the transition of private research in the United States move less from basic science into more downstream-related activities, a great deal of the force of laboratories like Bell Laboratories in the past will be now present in our national research universities.

So our national research universities are going to be increasingly important agents in our competitiveness posture. We are not completely sure how that should be shaped in the future so that we do not harm or destroy what is great about the university research environment. But, clearly, in the kind of knowledge-based economy that we are in today, our national research universities will be key competitive factors of our future.

Chairman HATCH. Thank you.

Senator Feinstein.

Senator FEINSTEIN. No questions.

Chairman HATCH. Let me just ask one other question, then. It is my understanding that the PTO is currently engaged in international harmonization negotiations. Some have expressed concerns that if Congress pushes ahead with international harmonization of the patent system before these negotiations are concluded, it will undercut the United States' negotiating position. This seems to be a real problem to me.

In your opinion, should Congress hold off on harmonization?

Mr. LEVIN. I would offer the point that I think it is in the unilateral advantage of U.S. companies to harmonize; that is to say, no, Congress should not hold off. The things we are proposing in many ways are simply going to be better for firms that are trying to do business around the world. It is going to simplify their lives to operate under one standard, such as the first inventor to file, and save lots of litigation costs right here in the United States. So we think you should go ahead.

Chairman HATCH. As you know, there is a hearty debate taking place over how to change the injunctive relief provisions of the Patent Code. Do either of you have any views on this matter?

Mr. LEVIN. The committee didn't take a position on this.

Do you have a personal view?

Mr. MYERS. No, I would rather not offer a personal position, but we did not discuss this subject.

Chairman HATCH. Let me thank you and the rest of your panel and staff and outside consultants and participants for all the hard work that you have done in producing the NAS report.

Can you give us a sense on what you believe are the highest priorities among the seven key recommendations in the NAS study? Let me just put it this way: If there was one thing that Congress could do to make the patent system better in the future, what, in your opinion, would that be? Similarly, if there were one thing that you could prevent from happening legislatively, what would that be? I would like to have your best advice on those two issues.

Mr. LEVIN. Well, I am very partial to the idea of the post-grant review system. In an environment where technology is changing very rapidly, such as the Internet business patents that were filed in the late 1990s, or at an earlier time genetic patents, having the capacity to quickly determine what kinds of patents are going to hold up, what kinds of patents are going to be valid, is going to create such a stronger environment of certainty for the industrial sector that you will see a more rapid pace of innovation.

People won't hold back in making investments because they are worried that they are infringing. On the other hand, people won't make wasteful investments that turn out to be invalid later. Having a timely way to really test an emerging area of law, which is always the case when there is a new technology—there are new questions to resolve—is very, very important. I would say that is the most important of our recommendations.

Chairman HATCH. Thank you.

Mr. MYERS. I would agree with that. I think that I would put it under patent quality. I think patent quality is extremely important, and I think the post-grant review enables that. I would have to slip in, if you would allow me, that international harmonization, as rapidly as we can move there, is a very close second.

Chairman HATCH. Well, thank you very much. We really appreciate you both taking time from your busy lives to come down here and help us try to understand this a little bit better. Thank you very much.

Mr. LEVIN. It is an honor to help. Thank you.

Mr. MYERS. Thank you.

Chairman HATCH. It is an honor to have you here.

We will turn to our third panel now: William Parker, of Diffraction, Limited, in Waitsfield, Vermont; Dean Kamen, President of DEKA Research and Development Corporation, in Manchester, New Hampshire; David Simon, Chief Patent Counsel for Intel Corporation, in Santa Clara, California; Robert A. Armitage, Senior Vice President and General Counsel for Eli Lilly and Company, in Indianapolis, Indiana; Joel Poppen, Deputy General Counsel of Micron Technology, Inc., in Boise, Idaho; and Michael K. Kirk, Executive Director of the American Intellectual Property Law Association here in Washington, D.C.

Mr. Parker, we will begin with you.

STATEMENT OF WILLIAM PARKER, CHIEF EXECUTIVE OFFICER AND DIRECTOR OF RESEARCH, DIFFRACTION, LTD., WAITSFIELD, VERMONT

Mr. PARKER. Mr. Chairman, Ranking Member Leahy—I guess he stepped out of the room—and members of the Subcommittee, my name is Bill Parker and I am Chief Executive Officer and Director of Research for Diffraction, Ltd., a technology and intellectual property-based small business in Vermont. Thank you very much for inviting me to testify today on this most important topic.

In my testimony, I hope to present some of the views of individual inventors and other small entities on needed changes to the United States patent system. As evidenced by the substantial numbers of innovations and patents that spring from small businesses around this great country and the jobs that these innovations create or maintain, these small-scale operations have a significant role to play in the United States economy.

My company, Diffraction, Ltd., is not just small, it is a micro business. This panel's members are by and large from large entities or represent groups of patent-holders. I will try to make this presentation as focused as possible on a few issues of patent reform as they affect individuals and small businesses.

Like many small technology-based businesses, our company was founded by an inventor and patent-holder. In our case, it was my wife Julie. After earning a graduate degree from MIT, having little or no business background, she decided to start her own company to further develop and capitalize on her skills, talents, inventions and discoveries.

She thought it was useful to have a partner in this endeavor, and that is where I came in. As an inventor from childhood with some reasonable commercial successes, I had collected a considerable range of experience learning about the things one did and did not do to capitalize on one's creativity. Fifteen years later, we have three little inventors at home and a company with a staff of 20 innovators. We have produced a number of commercially-viable developments and patents in holography, optics, micro electronics and nanotechnology. We recently launched an effort to develop innovations that may help win the war against terrorism, work supported with Federal government contracts as well as private funds.

It is important to note that we believe our intellectual property in the long term will have value than our tangible output will in the short term. Said a different way, the product of our minds

probably has more value than the things we can make with our hands.

When we have done our inventing job well, we may need to depend on others to take our innovation to the market. Like other inventors that choose the licensing route over manufacturing, we then ask for a royalty payment as a return on our investment in the innovation.

That the United States is moving toward an economy where money generated from intellectual property is a significant element of the GDP is undeniable. That we are doing everything we can as a country to protect our IP is questionable. The future world market will need new rules regarding the ownership of ideas, rules that need to be fair and balanced. We would like to offer an image to the Subcommittee of a day when the U.S. has little to offer other than intellectual property, a few raw materials and some farm produce. This is a scary scenario if we are not prepared or able to protect our most important assets.

On the quality of patents—this is the number one issue, I think, for all inventors—the patent process must be flawless for a patent to be above question, and it must be above question to have any real value. As the art becomes more involved and specialized, it is increasingly more difficult to factor out mistakes of omission. Better access to prior art is part of the solution, but more is needed in the examination process to prevent a poor outcome despite a significant amount of time and money being spent.

Redirecting PTO fees is not part of the solution. Money not spent by the PTO to ensure quality is often spent instead by the patent-holders and their challengers in legal actions. Tremendous amounts of money are spent in challenges, when a fraction of that could have been spent better to prevent the problem at its source.

There is a need for skilled examiners in emerging technology areas, keeping in mind that experts in their specific art are, in fact, their customers. From biotechnology to nanotechnology and software and micro electronics, as well as other cutting-edge fields, the experts are the ones making the inventions, not the ones determining if they are, in fact, inventions.

On first to file versus first to invent, it sounds like a good approach in many ways for individual inventors, for harmonization and for the system in general. But, in fact, it poses a few big problems for small entities. It would be very difficult, but not impossible, to change the system and not disadvantage small inventors. Due to the high cost of building prototypes or doing laboratory work, it takes a small inventor a reasonable amount of time to go from idea to reduction to practice. The ability to submit continuances in part and amend claims are the other tools available to small inventors.

We would like to see ways to encourage the creativity and capabilities of our country's small inventors, but reduce their cost in obtaining patents, while still giving them protection in the world market. As far as injunctive relief, we don't believe that all inventors are opportunists or patent predators, even though a lot of talk is aimed at protecting big businesses from the actions of a few opportunists who try to use the system against itself.

In conclusion, I speak for many of my colleagues and small entities when I thank the Subcommittee for this opportunity to be able at the table for this hearing. We only ask for more chances to provide views to Congress on this important topic and for more presence on advisory boards during the patent reform debate.

I personally thank you for the opportunity to be here before you today, Mr. Chairman, and I offer my continuing efforts to find or invent ways to make our patent system work for the 21st century and beyond.

Thank you.

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

Chairman HATCH. Thank you, Mr. Parker.

We will just go across the table.

Mr. Poppen, we will take you next.

**STATEMENT OF JOEL L. POPPEN, DEPUTY GENERAL
COUNSEL, MICRON TECHNOLOGY, INC., BOISE, IDAHO**

Mr. POPPEN. Chairman Hatch, Senator Leahy and members of the Subcommittee, I am the Deputy General Counsel for Micron Technology. Thank you for allowing me to testify today on the very important issue of patent reform. Since my submitted testimony covers a number of issues in some detail, I will focus on just a couple of major points today.

Micron is one of the world's leading providers of advanced semiconductor products. Our products are used in today's most advanced computing, networking, communications and imager products. Micron's investment in R&D has led to over 12,000 U.S. patents, and in the past five years Micron has been among the top ten recipients of U.S. patents. Accordingly, Micron is a significant stakeholder in the patent system and has a keen interest in its improvement.

In recent years, opportunists have exploited the patent system to attack those who innovate and manufacture products. According to studies, this trend has led to a 60-percent increase in patent suits in the last decade and staggering costs. As authors Jaffe and Lerner note in a recent book, quote, "Burgeoning patent litigation is increasingly making lawyers the key players in competitive struggles rather than entrepreneurs and researchers. As the patent system becomes a distraction from innovation rather than a source of incentive, the engine of technological progress and economic growth begins to labor," close quote.

To curb the growing abuse of the patent system, to realign the intended incentives and to restore fairness for everyone, the patent system should be reformed through targeted legislation.

First, manufacturers increasingly are coming under attack from those who are inventing patents rather than patenting inventions. These inventors of patents use continuation practices in the patent office to tailor patent claims over time to cover the activities of others. Later, they surprise manufacturers who are locked into technologies with unanticipated patent claims and steep royalty demands. To redress the patent problem, patent applicants should be required to file their broadest claims very early in the process and

should not be allowed to later claim broader or different inventions after watching the activities of others.

A second problem area relates to significant judge-made advantages for patent plaintiffs. When plaintiffs prevail, courts virtually automatically enter an immediate injunction shutting down a defendant's business, even though the applicable statute plainly requires that principles of equity be weighed first. Courts simply short-cut the analysis by presuming that the plaintiff will suffer irreparable harm if an injunction does not issue. But many patent plaintiffs are in the business of only collecting royalties and money damages are sufficient to fix any harm. To ensure the proper balancing, the patent injunction statute should be amended to instruct courts to weigh all the equities before issuing an injunction.

A final area of problems relates to excessive damage awards. Patent opportunists use system claims and court-sanctioned damage theories to claim damages on entire products even when only a small part is the actual invention. Accordingly, the patent damages statute should be amended so that damages are limited to the proportion of the value directly attributable to the invention rather than the larger system in which it resides.

Additionally, defendants almost always are faced with allegations of willful infringement and the threat of triple damages. But since enhanced damages are punitive in nature, they should only be available upon an express finding that the defendant's conduct was egregious or reprehensible.

In conclusion, targeted manufacturers often face a Hobson's choice: daunting litigation costs, slanted evidentiary standards, exorbitant damage awards and virtually certain injunction relief on the one hand, and predatory licensing demands on the other. Patent reform legislation is essential to restore fairness and to protect the integrity of the patent system.

Thank you again for the opportunity to provide some perspectives on patents.

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

Chairman HATCH. Well, thank you, Mr. Poppen.

We will turn to you, Mr. Simon, and take your testimony.

**STATEMENT OF DAVID SIMON, CHIEF PATENT COUNSEL,
INTEL CORPORATION, SANTA CLARA, CALIFORNIA**

Mr. SIMON. Thank you, Mr. Chairman. My name is David Simon. I am the Chief Patent Counsel of Intel Corporation and I am here to testify on behalf of the Business Software Alliance. Our group contains not only some of the largest patent-holders in the United States, but we also contain many small patent-holders, and I am here to talk about the imbalances that arise from complex products that contain often billions of components or billions of lines of code that are alleged to be touched upon by thousands of patents.

It is our belief the patent system needs some adjustment to meet the needs of our industry. In addition to being overwhelmed by new applications, which have caused a five-fold increase in backlog in patents, the PTO also faces a deluge of continuation applications. I believe it is about 25 percent, according to Director Dudas.

Patentees file these continuation applications even up to a decade after the original filing date, filing to stretch their disclosures to claim evolving technology or standards. They then tax the industry with what can only be viewed as inventive patents. Then, once issued, the procedures by which the PTO can review the validity of these patents are inadequate.

Ex parte reexamination has proven futile over 85 percent of the time. Why? Because after filing the request, the requester is no longer participating in the process. The patentee will then narrow the claims, while avoiding the prior art sitting there with the requester's product trying to make sure that the claims cover that.

We firmly believe that a robust inter partes opposition procedure needs to be there so the patent office can deal with the mistakes that overtaxed examiners will unfortunately make, particularly if, as Director Dudas said, we are going to have 25 percent new staff. Specifically, inter partes reexamination should be fixed by removing the time limitation on patents that may be reexamined and by fixing the collateral estoppel provision in Section 315(c) of Title 35.

In addition, we firmly believe in a meaningful post-grant opposition procedure. We do not believe that a nine-month window, however, is sufficient, as advocated by others. We think that there needs to be a second window because, unfortunately, with the speed with which our technology moves, it could be years before we realize that a patent that issued years ago might be significant or not.

While we support the efforts to improve the patent office's internal procedures, we also believe that it is important to fix major problems that have cropped up in litigation.

First, the law of triple damages and willful infringement needs to be fixed. We believe these are punitive damages and they should be reserved, according to the standards set forth by the Supreme Court, for cases of reprehensible conduct, such as intentional copying of a patent without a good-faith belief that the patent is inviolate.

The current gamesmanship of letters or the gamesmanship of artfully drawn letters that are advocated by some other organizations has little to do with ferreting out reprehensible conduct. Instead, it creates hardships, including forcing a defendant to choose between defending against triple damages, on the one hand, or on the other hand waiving its attorney-client privilege. These hardships are used by clever litigants seeking only to maximize the settlement value of their cases.

Second, the BSA supports adding certainty to the measure of damages on complex products. Today, when a small feature of a multi-faceted product is alleged to infringe a patent, the patentee will often claim that they are entitled to the entire market value of the good rather than the value of their little patented feature. We believe that reform is needed to rein in these excessive damages.

In addition, the BSA supports clarifying the jurisprudence regarding injunctions. The law today directs the courts to balance equities before issuing an injunction. Nonetheless, essentially the only reason that courts frequently will cite for not granting an injunction is in the face of a national health emergency. That inter-

pretation of the public interest risks turning equity into a needle's eye which is very difficult to meet.

All of these issues have led to a new business model of acquiring control of patents from distressed companies and then suing American manufacturers in plaintiff-friendly jurisdictions, with the threat of inevitable permanent injunctions and high damages at the end of the case to extort settlements.

The defendant is thus threatened with having its entire business shut down, and no matter how convinced we may be on the merits of our position, we cannot simply afford to take even a 10-percent chance of losing and having billions of dollars of business or factories worth billions of dollars being shut down.

We are aware of the concerns of some that this would undermine the exclusive rights of inventors, but there are persons who abuse these exclusive rights that run contrary to the equitable principles set out in Section 283 and to the fundamental goals of the patent system. What we are saying is that Congress needs to address these abuses by ensuring that equities are fully taken into account by the courts and the public will continue to see the system as fair and balanced.

Thank you.

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

Chairman HATCH. Thank you, Mr. Simon.

Mr. Kamen, we will turn to you.

STATEMENT OF DEAN KAMEN, PRESIDENT, DEKA RESEARCH & DEVELOPMENT CORP., MANCHESTER, NEW HAMPSHIRE

Mr. KAMEN. Good afternoon, Mr. Chairman and the other members of the Subcommittee. I appreciate having the opportunity to speak from the perspective of a small inventor.

By way of introduction, I really am a small inventor. I started my first business inventing in the basement of my parents' house. I was building audio-visual systems and then started building medical systems products for my older brother, who was then in medical school. At the time I started my first business, we actually did it all. We conceived it, we designed it, we developed it, we manufactured it, we marketed it, sold it, serviced it.

As our medical products company grew, we learned a bunch of things, one of which was all of that takes a lot of work. After about a decade of doing that, I sold that business to a major medical products company in this country and decided that we should focus on what we really do well, which is conceive of solutions, design them, develop them, make sure they work, and then try to align ourselves with large companies that have the reach and the scale in terms of manufacturing, distribution, sales and support so that our technology could get out to the people that need it.

I started a company to do that 20-some-odd years ago, and over that period of time we have built home dialysis equipment which is used all over the world, stents and many other kinds of products. I think that system works for everybody. We can focus on what we do very well. Our corporate partners can get these products much more quickly and much more cost-effectively to people around the world.

The only bug in all of that is we turn these things over and even though my company now has 180 people working in it, since we don't have a brand name, we don't have distribution, we don't have manufacturing, what we bring to the table is the solutions to these problems broadly represented in patents. It is what we have. We are an intellectual property company. Almost our entire revenue stream is derived from the royalties we get by licensing our partners to be able to make these products. I really think it is a win-win-win, and it is what the Founders had in mind. Patents were there to encourage people to take risks to invent things. We focus on doing precisely that.

Since I only have about two minutes, I guess I would like to restrict my remarks then to two issues. One which is sort of down in the weeds—and I know a little bit about it because I have been recently made a member of PPAC, the Public Patent Advisory Committee, in which I have had an opportunity to see the patent office from the inside.

One of my issues then would be to say we have got to make sure the quality of patents is kept high. We have heard different people talk about staggering numbers, Jon Dudas pointing out that they are 400,000-some-odd behind, so to speak, in pendency. But, frankly, a problem like that for most private companies would be an embarrassment of riches. The whole world is now seeing the importance of patents. There is enormous growth and demand for these patents.

That is a problem a lot of companies would like to have, but the way a company would resolve that is they would quickly grow, put resources to it and hopefully not allow the quality of that company's products to suffer as they dealt with this great growth opportunity.

I would urge you—and I heard you say that in your opening remarks—to make sure, for instance, that there is no diversion of fees away from the patent office, not at a critical time like this, but to do everything you possibly can to make sure that the quality of patents is kept high, because if there is no quality there, there is nothing there. When you hold up that patent that you have worked for years and spent millions of dollars to develop, it is in everybody's best interest that it is a quality product.

My second issue is speaking not as somebody who knows the inside, but just as a citizen, an inventor, not a lawyer, on this issue of dramatically weakening the value of patents by removing the presumption of injunctive relief. The idea that my patent gives me exclusive rights to my own property is pretty clear.

I mean, the Constitution, as has already been pointed out, doesn't say I have the right to my idea. I don't need the Constitution to give me the right to think. What it gives me is the exclusive right to my idea so that after I show the world what it is, they still, for a limited period of time, need to come to an agreement with me to exploit it. If we eliminate my capability to give an exclusive right to my invention to my partners, it will be very difficult to get investors or large corporations to invest the time and money, many times millions of dollars, in developing new products if they are being asked to uniquely invest in these ideas, but in the end they don't get a unique and exclusive license to it.

If we take away the right to prevent other people from exploiting our technology, a patent would be nothing but an empty promise, and I hope that that doesn't happen because I think we all know that intellectual property and investment in it are what drive this economy. And in the next century, they will be the primary driver of the economy of the United States.

Thank you.

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

Chairman HATCH. Thank you.

Mr. Armitage, welcome back to the Committee. We are glad to have you here.

STATEMENT OF ROBERT A. ARMITAGE, SENIOR VICE PRESIDENT AND GENERAL COUNSEL, ELI LILLY AND COMPANY, INDIANAPOLIS, INDIANA

Mr. ARMITAGE. Chairman Hatch, I am delighted to be back. Senator Leahy, thank you very much for allowing me to appear here today.

Dean Kamen gave a very impassioned speech and relatively preempts the first part of what I was going to say. We had a chance to talk very briefly before the hearing began and I discovered that he and I are partners, unbeknownst to me.

One of his pumps was a pump that is used in one of our high-tech insulin devices, and the ability to marry a high-technology delivery system with a high-technology insulin product literally changed the lives of patients who use our drug. I know this because one of my first experiences as a Lilly employee was practically being tackled by one of our patients at an evening reception telling me how much her life had changed.

So, Mr. Kamen, thank you.

I want to address perhaps three areas. I would like to talk a little bit about what I think the highest priorities are for patent reform. One area is I would like to provide a cautionary flag on a reform that I really do believe is important and desirable, and then there really is one area where I need to ask the Committee to proceed with great caution before making a change to the patent system.

Because this last area is the one of most importance to the pharma-biotechnology industry, I would like to begin with it first, and that deals with the issues of injunctions and damages. As you have heard, Congress is being asked to consider whether to deny an injunction to the owner of a valid patent who can't make an affirmative showing that he has been irreparably harmed. Also, the proponents, BSA, of this proposal have paired it with a second one that would impact the provisions in the patent statute that guarantee the patent owner the right to adequate compensation when a valid patent has been infringed.

Lilly would urge Congress to take these two proposals off the patent reform table. Congress simply should not compromise on the principle that absent some overarching public interest, demonstrating ownership of a valid patent property right should be the only showing needed to stop someone from trespassing on that right. In a similar vein, no owner of a valid patent should be de-

nied adequate compensation when a valid patent has been shown to have been infringed.

I would now like to just raise a couple of cautionary flags. You are being asked to consider a new post-grant review procedure for issued patents beyond the two such procedures that are already in the patent statute. This perhaps is the most important reform of all the reforms that we have been talking about today.

However, experience in other countries should provide some sobering realities. In Europe, oppositions cost enormous amounts of money and can take years and years to conclude. Their system clearly is not a model for our emulation.

The new capabilities that the office will need to implement these oppositions could be staggering. If you just assume that 1 percent of patents will be opposed, which is far fewer than the percentage of oppositions you see in countries outside the United States, it could perhaps take years for the Patent and Trademark Office to assemble a cadre of experienced administrative patent judges who would be able to efficiently handle these procedures.

Also, Lilly has been at the forefront of support for creating a nine-month window for post-grant oppositions, and it is clear to us that it will be a huge challenge to get a nine-month post-grant opposition window law done just right. However, the proponents have much more ambitious proposals that wouldn't limit the right to seek an opposition to just this nine-month window. We frankly see no possibility that giving the patent office expansive jurisdiction over all issued patents potentially at any time in their life could possibly make sense at this juncture.

As a last point, there really is no other country in the world that attempts to couple a post-grant opposition system with the complexities we now have in our law as a result of the "first to invent" principle, and indeed it is far from clear that unless we are prepared also to move to a "first inventor to file" system that a post-grant opposition system here could be successfully implemented.

Now, let me move on to the top areas that I see for patent reform and suggest that we may rally around Director Dudas' call for reforms that make the work of the patent office easier. In this respect, I would suggest we look at four areas.

One, of course, is the "first inventor to file" reforms that eliminate the need you have heard about today for the office to consider invention date proofs and conduct patent interferences. Second are the other best practices reforms that would eliminate other tests or conditions for patentability that also make the work of the office more difficult.

Third, we need to rein in the inequitable conduct defense, which in Director Dudas' statement is quite clearly responsible for a lot of the defensive patent prosecution practices that he bemoans and that make the work of the office more difficult. Fourth, it truly is important for Congress to find a way to stop continuing application abuse. They are now about a third to a quarter of all the work in the patent office.

The time is right for reform, and from our point of view we are just delighted to be here providing our perspective and hoping to be able to work with all the constituencies to move this process forward.

Thank you.

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

Chairman HATCH. Thank you, Mr. Armitage.

Mr. Kirk, we are always happy to have you here. We will take your testimony.

**STATEMENT OF MICHAEL K. KIRK, EXECUTIVE DIRECTOR,
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION,
WASHINGTON, D.C.**

Mr. KIRK. Thank you, Mr. Chairman and Senator Leahy. I am pleased to have the opportunity to present the views of AIPLA on the need to improve the U.S. patent system. My complete statement sets forth the convergence of the recommendations by the Federal Trade Commission, the National Academy of Sciences and AIPLA for addressing this need and the proposals that AIPLA has developed based on these recommendations.

These proposals were explained to stakeholders across the country in three town hall meetings cosponsored by NAS, FTC and AIPLA, and we refined our proposals to reflect the input that we received following these town meetings. There will be a fourth meeting in June of this year here in Washington to wrap up this proposal and further attempt to educate and involve all stakeholders.

On the basis of this effort—and I must say, being last, there is a certain amount of repetitiveness, but I will try not to dwell on this—we believe that a coordinated and interrelated set of reforms should be made to the patent system; adopt the “first inventor to file,” we have heard; eliminate the subjective elements of patent litigation, as President Levin said earlier and Mr. Armitage just said; complete the desirable legislative enhancements in the American Inventors Protection Act, that is mandate the publication of all applications at 18 months; and, finally, adopt a fair and balanced post-grant opposition system that takes advantage of the elimination of the subjective elements in patentability criteria that follow the elimination of a “first to file” principle.

AIPLA would like to highlight the most fundamental problem in need of a solution. Of course, you, Mr. Chairman, are well aware of this, and that is the urgent need for adequate and stable funding for the PTO. Both NAS and the FTC agreed with the user community on this crucial point, as pointed out earlier this afternoon. The reforms that AIPLA and others are proposing will require that the USPTO play a greater role in the overall patent system, a role it cannot play unless adequately funded.

Let me turn now to a few of the other reform proposals mentioned today, if I might. First, perhaps of most concern to AIPLA is the proposal to preclude a court from granting a permanent injunction for a valid and infringed patent. AIPLA believes that this proposal would essentially destroy the exclusivity of patents, as suggested by Dean Kamen earlier.

This impact is going to be especially hard, in our opinion, on universities and independent inventors, who already face great difficulty in getting their patent inventions commercialized. It would be extremely unfortunate also internationally for the United States

to suggest that there may need to be no exclusivity for inventions that aren't worked in the local marketplace. I spent a lot of my first career traveling around the world to fight against this, and this would be a suggestion we feel that would move in this direction.

We do believe that there are opportunities for addressing some of the concerns that have been expressed by BSA or others. Whether or not these will be to their satisfaction remains to be seen. For example, where a court refuses to stay a permanent injunction pending an appeal, there may be some room to think about alternatives here. However, we strongly believe that a valid and infringed patent should enjoy exclusivity.

Another proposal discussed today was the abusive use of continuations. We believe that it is appropriate to consider a targeted solution to these truly abusive practices. However, the solutions that we have seen to date in proposals are too draconian. They would deny any possibility of broadening claims before applicants will even have received the results of an examiner's search of the claimed invention to know what scope of claims they might be entitled to receive.

In the effort to deal with a few bad and indeed abusive actors, we believe that these solutions that we have seen would unfairly preclude the legitimate efforts of most inventors to obtain the full measure of protection for their inventions which they deserve.

It has also been mentioned that there is a proposal to limit damages. This is the situation where a small component of a larger machine is patented and found to be infringed. It is proposed that somehow this is resulting in damage awards that are out of proportion to the value of the small patented component.

We understand that there are cases that may go in this direction, but also there are many situations that are addressed in current case law. One of the written statements earlier mentioned the Georgia Pacific case where there are 15 factors that courts routinely consider, and there have been cases where the courts have taken these factors and addressed cases to properly balance the award, be it on the entire value of the product or be it limited to the specific component. This has occurred also in cases where the component was actually claimed in the patent as part of an overall, entire product, and courts have been able to look at this and deal with this. So we are concerned that we not unfairly and unnecessarily limit the value-added to these damage awards.

Finally, there is a proposal that we have seen that would reverse the decision of the Federal Circuit in *Eolas Technologies* and the *Regents of the University of California v. Microsoft*. This proposal would limit the definition of the term "component," as used in Section 271(f) of the patent statute, to a tangible item that is itself physically combined with other components of the patented combination.

It is argued that this interpretation creates an incentive to move software development outside the United States. Assuming there is evidence to support this, one might ask whether or not the *Eolas* case would have similar consequences for tangible components; that is, should we, in fact, revisit 271(f) entirely and should it now be repealed in light of today's trading situation around the globe?

I thank you for the opportunity to present the views of AIPLA and I would be happy to attempt to answer any of your questions.

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

Chairman HATCH. Well, thank you so much. We appreciate this whole panel. It has been very interesting for us to listen.

Mr. Kamen, let me just start with you. I always salute successful people who take the time and make the effort to give back to society.

Senator LEAHY. I think, Mr. Chairman, we should have both come in on a Segway here.

Chairman HATCH. Yes, that right.

Senator LEAHY. The last time I saw him, we were riding them together.

Chairman HATCH. Well, I was able to ride one of those pretty well. I liked that a lot, I will tell you. We need Segways for every Senator to get back and forth to the floor. I think it would be very helpful to us. We would probably be rolling over people, though, knowing some of the people around here and how athletic they are.

Tell us what you were doing in Atlanta this weekend. You are a person who does give back.

Mr. KAMEN. This weekend, I had the final event—and by the way, Senator, you are going to get homework out of that event. I met three teams from your State who said they are determined to have one of our events next year in Utah. I told them to personally get to you as quickly as they could.

Chairman HATCH. I am surprised you haven't come to Utah. We have more patents than any State in the Union, you know, and it is a nice atmosphere.

Mr. KAMEN. Well, these three teams are going to send you some pictures and some great memorabilia.

We run a program, a non-profit, that tries to convince students while they are still making career choices that science and technology and engineering are every bit as much fun and accessible and rewarding as what are typically put in front of most kids these days, the world of sports and entertainment.

In order to compete with sports and entertainment with our program, we make it a very exciting sporting event. We have grown to the point that we have a 1,000 high schools around the country competing in 30 cities, and that happened throughout each weekend in March. We took over the home of the 1996 Olympics, the Georgia Dome, in Atlanta, this weekend and about 30,000 engineers, 1,000 corporate sponsors behind them, and all of these high school students showed up to be in this robotics competition, in which what they are really doing is learning how much fun and excitement and reward there is for kids that will put passion into thinking and creating and problem-solving.

I can also tell you that I asked the Director of the United States Patent Office to show up there and convince these kids that they are his next generation's customer, and he did an extraordinary job, I think, of energizing all these kids about the prospects of being inventors and carrying the tradition of the United States as a world leader in technology forward.

I had one other speaker who might be relevant to the patent office. I convinced Larry Page, one of the founders of Google, to come out, and he stood on stage and pointed out to these kids that his company which he started in college has now got a market cap of \$50 billion. He doesn't make anything that is physical. He is an intellectual property company. I think he is a poster child for that. These kids certainly responded to that. It was a great event. I hope that we will have events in Utah next year. I thank you for asking.

Chairman HATCH. I hope so, too. Thank you.

Let me just ask this. While it appears that there are many issues upon which there is consensus for patent term reform, one area in which there appears to be substantial disagreement is with respect to changing the standards for injunctive relief under the Patent Code.

I see that BSA and AIPLA and Mr. Kamen have different positions on this issue. Before the Congress chooses an option, should it do so, it would be helpful for us to more fully understand not just your respective positions, but your respective interests. So please help us define the issue and why it is important to your various industries and tell us where you find mutual interests and where you find conflicting interests.

We can just start with Mr. Parker, if you would care to respond. You don't have to respond, but anybody who cares to, from our left to my right.

Mr. PARKER. Thank you. I think the comments that Dean Kamen made on injunctive relief are pretty universal among individual inventors and small entities. By the time you have a patent, you have worked very hard. You have risked a lot both personally and in your finances and in your time and in your energies.

It might be the one invention that you have made that will eventually make some money. You need to have every tool in the toolbox to be able to prevent someone from infringing that and you be able to recover your rights that you have lost from an infringer. And having strong injunctive relief is the answer to those problems.

Chairman HATCH. Thank you.

Mr. Poppen.

Mr. POPPEN. Well, Micron finds itself on both sides of this issue. We are both patent plaintiff and patent defendant in some circumstances. So we come at this understanding that it could impact us on both sides. The reason that we focused on it in our comments is that it is one of the most critical issues to us that we see on a day-to-day basis in real-world situations.

There is a model that is developing that Mr. Simon referred to of essentially professional patent predators who are buying patents and exploiting them against manufacturers. The one thing that they point to, and increasingly publicly so, is the benefit that they enjoy of the threat of an injunction.

For businesses like Micron and Intel and others, ultimately at the end of the day we need to advise our CEOs as to whether we can litigate a patent even when we think that it is a patent of little substance. We are faced with the prospect of saying if we lose here, we face a virtually automatic injunction.

I think it is important to note that what we are really asking is for the statute to be returned to where it started. The statute itself, the existing Section 283 injunction, in fact, calls for weighing principles of equity. Over time, that has evolved into essentially skipping that step and saying that it is automatic.

The other thing that I think is worth noting is that this isn't to say that in most circumstances an injunction wouldn't be appropriate or wouldn't be available. All that it says is that in appropriate circumstances you weigh the equities. If, for example, it is a licensing outfit that all they do is license their technology to a number of different companies, they clearly are in the business of collecting royalties. It is very clear that there is no advantage to them in shutting down a company. What they really want to do is use that as a lever to extract larger dollars than they otherwise would be able to if we could fairly litigate the merits of the patent. That is why we are in favor of the change to the injunction statute.

Thank you.

Chairman HATCH. Thank you.

Mr. Simon.

Mr. SIMON. I agree with much of what Mr. Poppen said, but I would like to give the Subcommittee a very specific example. A few years ago, we were sued by a company over a patent that they had acquired for \$50,000, and they immediately turned around and demanded \$5 billion for settlement, saying that—

Chairman HATCH. Is that million or billion?

Mr. SIMON. That was billion, Senator.

Chairman HATCH. Billion, with a "b"?

Mr. SIMON. Yes, \$5 billion for settlement, and threatening us with, you know, we will just take it to trial and we will get an injunction and we will shut you down and then you will have to pay us the \$5 billion.

Fortunately, we have happened in that case to be in a forum where we had a judge who would consider summary judgment on some very complex technology. We thought we were in a very good position. We won that case. Summary judgment was affirmed.

However, there are many fora in this country where there are judges unfortunately who are hesitant to grant summary judgment, and even some where they refuse to grant summary judgment in patent cases. There are some forums where there has been, for example, a track record, over 8 years, 50-some-odd cases with plaintiff verdicts and no defense verdicts. It makes it very hard, when you are looking down the barrels of an injunction, to take the case to trial.

It is very hard to go to your management and say I have got billions of dollars in factories at risk that could potentially be shut down. And they say to you, well, how often has the defendant prevailed in this forum, and you say, well, in the least eight years, Mr. Chairman—it is a different chairman, by the way—zero. That is why this is the most important issue for Intel and this is the most important issue for the Business Software Alliance members.

Thank you.

Chairman HATCH. Thank you.

Mr. Kamen, we know your point of view, but if you would care to say anything about this.

Mr. KAMEN. I would just say that I would be totally sympathetic to eliminating bad actors. Bad actors in any field hurt all the good actors. There are people taking steroids in baseball and I know that the Senate is considering what to do about that, but I haven't heard them talk about shutting down the national pastime of baseball. They go after the people who take the steroids. They don't destroy the game.

Chairman HATCH. We have come close a few times, I have to say. [Laughter.]

Mr. KAMEN. Well, I would simply tell you that taking away the right of the owner of a piece of property—and know you have put the preface “intellectual” property, but unless that word “intellectual” is supposed to make it sub-standard or less important than any other kind of property—and I think, quite the contrary, in the future it will be the important—after a person has worked to develop that property and has a valid patent, and after somebody has had the right and opportunity in the courtroom to challenge it and loses, and only after they lose, the person who has gone through all of this that has this piece of property should have the right to use it or dispose of it as they see fit, as we do with any other property.

Anything that changes that essentially is equivalent in a patent system to compulsory licensing, which this country has rejected at every opportunity it can on a global scale. I think we should go after the problem and we should not wipe out a system that for 200 years has made us the envy of the world.

Chairman HATCH. One of the problems is the court system. When you have a hundred percent granting of injunctive relief, even the most serious plaintiff's lawyer would have to acknowledge that that might not quite be kosher. So I can see the problem here. The question is how do we solve it.

Mr. Armitage.

Mr. ARMITAGE. I am in the pharmaceutical business, so I won't use the sports analogy, but I will use another analogy. I have tried to listened carefully to the BSA and I have concluded that there probably is a cancer on the patent system, but you don't get credit for killing off the cancer by killing off the patient.

The issue you have is are you going to kill off intellectual property as a property right. It is recognized under the Fifth Amendment as a property right. Congress needs to take that under consideration under the Takings Clause if it is going to affect any of the patents that are going to affect Business Software Alliance companies during the next decade.

But what is the cancer rather than the patient? I think the cancer we are talking about is patents commanding intimidation rather than patents commanding respect. Patents ought to command respect, but they ought not to be so intimidating because of the way the legal system works that you can't afford the business risk of taking on a potentially bad patent and, if need be, wrestling it to the ground. I think the dilemma we have is that we are not talking to each other about the cancer. We are talking about the future of the patient.

I don't want to prolong this discussion, but I just came back from a trip to India where I sat down with a senior government official

who told me that the Indian parliament had just passed a law that would stop us from enforcing some of our patents, but that was okay because we could go to the patent office and they would give us reasonable compensation, probably a couple percent of the selling price of the generic versions of our medicine.

You can do a quick mental calculation and realize that royalty stream, if we invested it entirely in innovative medicines, wouldn't be enough money to fund our Indianapolis research labs long enough to come up with a new medicine before the next ice age is likely to freeze them over. So my only plea would be it may be that there are some industries for which it is okay for patents not to be property rights. The pharmaceutical and biotechnology industries are not such industries.

Chairman HATCH. Thank you.

Mr. Kirk.

Mr. KIRK. Senator Hatch, the AIPLA is made up of attorneys from corporations and private firms. About a third of our members are corporate attorneys; two-thirds are private attorneys. We have discussed the issue that is before us here and our corporate attorneys have not been able to be sympathetic to the proposal that is being advanced by BSA. They believe that a company can adequately protect itself by looking at what is coming out of the patent office, by investigating the validity of the patents.

If, in fact, it is going to impinge upon one of their operations—and many of these companies have large, complex machines like, for example, Kodak, Xerox. If these companies see something coming, they either will reengineer, which advances the progress of the useful arts because we now have perhaps new inventions, or they will affirmatively go forward and seek a license.

Looking it at from the standpoint of the smaller inventors, however, small businesses and/or universities, we believe that, as Mr. Armitage said, this really is killing the patient to go after a few bad actors. We are certainly not against trying to address the problems that BSA has identified with the bad actors. We think this, though, is the wrong solution.

Chairman HATCH. Thank you. My time is way over.

Senator Leahy.

Senator LEAHY. I think these are important questions, and as I mentioned to you, I certainly have no objection to the actual time.

As some of you noted, I have had to go in and out a couple of times because of another matter that is going on. The other matter is work. This is the part that is really interesting, so I appreciate that I could come back.

I want to tell Bill Parker how pleased I am that he came down. Was it 1997 the last time you were before our microphones? Does that seem about right?

Mr. PARKER. I think that is about right.

Senator LEAHY. Eight years ago. Time goes by.

Mr. PARKER. It sure does.

Senator LEAHY. You were extremely helpful then and you are extremely helpful today. I appreciate you coming here. Your own perspective is as a small inventor, not just by being a Vermonter, but being a small inventor. But I think you are typical of many of the small inventors we have not only in our State, but in the other 49

States. As you know, some of those inventions end up being major factors in our commerce throughout the country, as Mr. Kamen and others have noted.

In your written testimony, you mentioned that moving the U.S. to a "first of file" standard is basically a good idea, but raises some concerns for the smaller inventors. Obviously, this is going to be one of the issues we are going to facing here, this "first to file." If you were sitting in those discussions, what are some of the things you would tell us to watch out for?

Mr. PARKER. Thank you for bringing that point up. The "first to file" has harmonization aspects to it that are positive. It has aspects of reducing some of the uncertainty about the pedigree of an invention. Some of those issues could be solved at a later date, for example, with a post-grant review process.

But, overall, I think the major differences, as I see them, are how that will affect the small inventor over the large inventor. In the final analysis, it all comes down to money. There are a lot of activities that occur in getting a patent cued up that drain an inventor. To think that they have time against them as well is a difficult proposition. And as many advantages as a small inventor can have, he needs.

Certainly, the provisional patent application process has helped to get an idea written down and into the patent office in a way that starts the clock. That certainly should be maintained, and any allowances that come out of the post-grant review for an argument to be finally sealed against an invention being valid should be considered also in a timely manner. I think it has been discussed a year, possible longer for that process.

I think we are more likely to see the small inventor run out of money by the time that process is over, if they have an active participatory role in the review, so shortening that or making it as inexpensive as possible for the small inventor to participate.

So to get to the heart of the question of the first to file, it is a major change in the way that inventors, particularly small inventors, would be going about their business, and there should be as many safeguards to protect them and level the playing field, if that is possible, if we go to that system.

Senator LEAHY. Thank you. You talked about the quality of the patents issued by the PTO. Certainly, we are all worried, and PTO is worried about it, the sudden huge numbers and how you keep up the quality.

What about permitting third parties to provide prior art to the patent examiners as they are examining a patent application? Would that help a small investor or would it make any difference one way or the other—a small inventor, I meant, not a small—well, a small investor, small inventor. Sometimes, a big investor is a small inventor.

Mr. PARKER. Yes. Very often, the small inventor is also the small investor in their own ideas. The entrepreneur is really the life that they are living at that point. They are taking all the risks from both sides, an emotional risk as well as a financial risk.

To have third-party involvement sounds like it is fraught with a few difficulties with bringing ideas that have been very carefully kept by the inventor to themselves. They are sharing it only with

the Patent and Trademark Office. They are only sharing it with others in a non-disclosure agreement. They are doing everything they possibly can to keep those ideas private. To bring in a third party that is now going to be looking over the shoulder of the examination process has those issues of confidentiality.

For a patent examiner to do their job well, they should have as many resources as they can, including consulting with experts, but not at the cost of the confidentiality that is expressed in a relationship they have with the inventor.

Senator LEAHY. You don't think they could write confidentiality agreements that could protect all the parties?

Mr. PARKER. Well, that is done today in many cases with the belief that a non-compete or a confidentiality agreement will be capable of protecting the holder of the intellectual property. Business works on that principle everyday. We probably sign two or three non-disclosure agreements a week that we believe are going to act to protect both parties in the business transaction.

At the scale that we are working with, going to a patent with a non-disclosure agreement as a form of protection for the inventor—I am not sure that that system is robust enough, nor has it been tested, but it certainly is worth reviewing. It is one of the many ideas that need to come forward in this process. There has to be perhaps some inventing of a new system based on not just taking old principles and reworking them, but coming up with some really new ideas. The world and its intellectual property value is changing. It is an exploding market for ideas and we are no longer at the tip of that spear. We have many others that we need to bring to the table in that process.

Senator LEAHY. Thank you. I have some other questions and I may write to you after this hearing to continue on.

Mr. Simon, you touched on this in the questions and all, but one of the concerns about current patent law is the threat of a court-ordered injunction that prohibits a company from selling products that are in dispute in patent cases.

When I think of Intel, some of your products can be cutting-edge today and can be outdated two years from now. I shouldn't say outdated, but you are constantly changing them. So the idea of having a product taken off the market for maybe a year or so while you litigate it is a great problem. On the other hand, if somebody has a legitimate complaint, they are looking for an injunction because they wouldn't want you—and I mean you generically—to be going and getting that market share that they will never get back.

So what do you suggest? How do you get the balance? I mean, suppose, for example, your company sees somebody going out for a product and you think you have a good argument that it is infringing and you want an injunction. On the other hand, you also face the problem that somebody may have an injunction, and they may have a legitimate injunction and they may have one, however, because they want to negotiate a settlement. How do you work your way out of this?

Mr. SIMON. Well, first of all, to be clear, we are not for the elimination of injunctions in patent cases. I just want to be clear on that point. Rather, what we are for is the application of equitable prin-

ciples to the determination of whether it is appropriate for the injunction to be granted.

From our perspective, you have to look at the situation. If you have somebody who has developed something, pushed it, worked hard on it and is seeking an injunction, that might be the appropriate thing for a court do in the circumstances. On the other hand, if you have somebody who went into bankruptcy court and paid \$50,000 to buy a patent and then is turning around and using it for a litigation business, that might be a case where a court would say maybe I shouldn't be granting an injunction. We think it should be dealt with on equitable principles. That is what the statute says and we think that that is the best solution for the problem.

Senator LEAHY. You said also in your testimony that software companies have to develop their products around other inventions that may be of dubious quality so you don't have litigation. Can you give me some examples of what you believe to be non-obvious software patents that have been asserted and forced software makers to react in that way?

Mr. SIMON. Well, other than the over a thousand that we own personally—

Senator LEAHY. I have heard the anecdotal, but can you think of some specifics?

Mr. SIMON. Software patents that are non-obvious?

Senator LEAHY. That have been asserted and then forced software makers to do this working around inventions of dubious quality.

Mr. SIMON. Well, the problem is my colleagues at other software companies don't disclose those issues to me, generally speaking, or to the extent they do, we are doing it under a non-disclosure agreement. For what we do at Intel, we would have the same problem. It is an issue. We do look at it. We do try to avoid infringement.

Senator LEAHY. What you are saying is you are not about to give an example here in this room?

Mr. SIMON. That is correct, Senator.

Senator LEAHY. Well, just say so. Orrin and I are reasonable people. We never frighten people, I don't think.

Mr. Armitage said that the Congress shouldn't change the burden of proof at trial for proving a patent is invalid. Mr. Poppen in his written testimony disagrees. He says that the preponderance of evidence is the standard in granting a patent and why shouldn't the same standard be applied in a patent challenge?

Mr. ARMITAGE. I am glad you asked me that question.

Senator LEAHY. I thought you might be. If it is a preponderance of the evidence—in my old business as a prosecutor, you had to prove it beyond a reasonable doubt, but what is wrong with a preponderance of the evidence being the standard all the way through?

Mr. ARMITAGE. Well, we are fair-minded in the pharma-biotech industry and we don't ask for beyond a reasonable doubt. We are willing to settle for clear and convincing evidence.

Senator LEAHY. Even though that is more than the original—

Mr. ARMITAGE. More, though, than a preponderance.

Senator LEAHY. It is more than what was required before to get the patent.

Mr. ARMITAGE. No, no. I mean, the current standard and the standard traditionally applied to patents in litigation has been clear and convincing evidence to invalidate a patent.

Senator LEAHY. I understand, but it took preponderance of the evidence to grant the patent.

Mr. ARMITAGE. Right.

Senator LEAHY. But you want more at a trial to prove the patent is invalid.

Mr. ARMITAGE. That is correct, and the reason for that—and maybe I will give you a couple of answers, but one has to go the pharmaceutical and biotechnology industry and I will just take the situation where we are going to buy some technology from a small company and they have invested a huge amount of money. We may invest another \$2 or \$300 million and then we may invest twice that much money in order to educate and develop physicians and educate a market so there is a market for that product.

We want to do that all that today fundamentally, as Senator Hatch well knows, on the strength of the patents that we have. And if it is tossing a coin in court as to whether that patent might or might not be held valid, it makes a much more risky investment. It makes our partners' portion of that much less valuable, and our willingness to pay and our willingness to invest that much less.

So there are industries for which patents are so important that it is absolutely critical, if they have gone through a rigorous process in the patent office and been found valid, that we have a patent that can be respected, not that intimidates, but can be respected.

Let me just say, as we talk about crafting a post-grant opposition system, we are talking about many proposals, notably the proposal of AIPPLA. Also, the American Bar Association's IPL section has a proposal that would say that in the post-grant opposition proceeding it would be only a preponderance of the evidence that the opposer would need to show.

Now, particularly if Congress were to take that step and not only have the patent office do a quality, rigorous examination, but allow an opposer to come in early within a nine-month window under a preponderance of the evidence standard, then it is absolutely to me categorically clear that a patent owner going through the trauma of examination and the rigors of an opposition ought to be able to bank on that patent in the courts and ought to have someone, if they wish to come later and challenge, come with clear and convincing evidence as to why that property right should be taken away.

Senator LEAHY. I think I understand your answer. I am going to submit questions to Mr. Kirk, but I suspect Mr. Poppen may want to say something.

Mr. POPPEN. I will be very brief. I think from our perspective if you talk about preponderance of evidence, it is a little different than saying flipping a coin. The reason for that is the realities of litigation are that the plaintiff, whether it is Micron or Intel or anyone else for that matter, has the opportunity to hold up a patent with a ribbon on it and say this was blessed by the patent office.

They also enjoy a presumption of validity. When you think about the realities of the patent office and the process, including the process that you mentioned that it issues based on a preponderance of evidence, what we are really saying is no matter what you do in the patent office, they will never be perfect.

To give a patent owner the advantage in litigation of being able to say it is presumed valid—all we are saying is the defendants really ought to be able to then take on the validity of that patent in a fair way. The reality is, as Mr. Simon mentioned, there are jurisdictions where jurors have a hard time taking on the patent office because based on the presumption and the level of proofs, they have a very difficult time thinking that the patent office ever makes a mistake with respect to a patent, including in situations where they don't have all the art in front of them. So the idea of a change in standard is really to give some fairness to the fight over whether the patent ought to be valid or not.

Thank you.

Senator LEAHY. Thank you, Mr. Chairman. I will submit the rest of my questions for the record. And, of course, everybody is going to have a chance to add in anything they want to, having heard everybody else's testimony. But I applaud you for having this hearing, Mr. Chairman. I think it is a good idea.

Chairman HATCH. Well, thank you, Senator Leahy.

We will keep the record open for questions until the end of this week, and we hope you will assist here because this is important stuff and we don't want to make any mistakes, or at least we don't want to make the usual mistakes. We will put it that way. But we can use a lot of help here and we surely think it is time to resolve some of these problems, and hopefully with your help we will be able to do so.

We are very grateful to have all of you here to take this kind of time to spend with us, and we will do our very best to try and sift through all of these problems and come up with patent reform that will be hopefully beneficial to everybody concerned.

With that, I am going to come down and say hello to all of you, but we will adjourn until further notice.

[Whereupon, at 3:53 p.m., the Subcommittee was adjourned.]

[Submissions for the record follow.]

SUBMISSIONS FOR THE RECORD



Answers That Matter.

Statement of
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company, Indianapolis, Indiana

Before

The United States Senate
Committee on the Judiciary
Subcommittee on Intellectual Property

On

"The Patent System Today and Tomorrow"

Monday
April 25, 2005



Chairman Hatch, Ranking Member Leahy, and Members of the Subcommittee:

Mr. Chairman and Ranking Member Leahy, my name is Robert Armitage. I currently serve as Senior Vice President and General Counsel for Eli Lilly and Company, Indianapolis, Indiana. Prior to joining Eli Lilly and Company I was a partner at Vinson & Elkins, where I was engaged in practicing intellectual property law. During the past three decades, I have represented individuals and organizations of all types and sizes seeking to defend and enforce patents, as well as challenge and defeat patents. I have also been involved in the work of a number of bar and industry trade associations, where I have played an active role in addressing patent reform issues. It is an honor for me to again appear before this committee to plead the case for major patent reforms to our patent system.

I intend to begin this afternoon with an explanation of just how vital the effective functioning of the patent system is to the pharmaceutical and biotechnology industries. I am, of course, aware that such an effort is entirely unnecessary. Mr. Chairman, more than 20 years ago, you led the effort to write the entire rulebook on how patents should work for the innovative pharma business. Those efforts provided the legal framework for the incredible pharmaceutical innovations of the past two decades. That rulebook, which is universally known as the Hatch-Waxman Act, has permitted the patent system to well serve both the pharmaceutical industry and the American public.

In addition, I would be most remiss if I did not further note your instrumental efforts in the fine tuning of the Hatch-Waxman rules that took place two years ago as part of the Medicare Modernization Act. The needed improvements to and clarifications of the Hatch-Waxman law that Congress enacted in 2003 now to serve the interests of both innovators and generic drug makers alike.

Let me begin, therefore, by briefly reiterating what you yourself have often observed. The investments that drive innovation in biomedical research exist today largely because the patent system operates to provide reliable and effective protection for that innovation.

The patent system provides the legal framework that drives the ability of the pharma and biotech industries to invest in basic research, discover potential new drugs, develop them into safe and effective medicines, and, once approved for marketing, educate physicians on their uses and advantages. Often, a multi-decade, multi-billion dollar investment is required to translate an idea into a medicine that proves successful in the marketplace. As you are aware, only a tiny percentage of new ideas ever become medicines and most new medicines never pay back the costs of the research needed to get them to market.

The patent system today affords broad and effective protection to all types of pharma and biotech inventions. It is the lifeblood for those making pharma R&D investments. The costs of the patent system today, although far from trivial, pale in comparison to its benefits for the industry and the public.



In this environment of high risk, the rewards of commercial exclusivity must be secure. Since these rewards are tied to patents that can be successfully and assuredly enforced, how the patent system operates in practice – in both the patent office and the courtroom – is a matter of the utmost importance to the survival of our innovation-driven business.

There is, therefore, much irony in hearing from a pharmaceutical industry witness on the issue of patent reform. We are an industry for which the patent system today serves our interests quite well. Indeed, it would be relatively easy for me to appear today simply to make a very strong case that the current patent laws serve the biotechnology and pharmaceutical industries so well that there is far more potential for harm than potential for good that can come from major tinkering with the patent laws.

The case for leaving much in our existing patent laws untouched is a quite easy case to make. Our patent laws today are the envy of much of the world. We combine a patent office that commands enormous resources and has substantial capabilities with a court system that can effectively handle the complexities of even the most difficult patent litigation.

Second, our patent laws, while imposing stringent requirements for patentability, nonetheless provide highly effective protection for those inventions that merit that protection. We have in place the institutions and the laws needed to lead the world in protecting and enforcing IP rights. Patent reform, therefore, is not about changes needed to permit the United States to assume a global leadership role. Rather, it is about how best to manage and expand that global leadership.

Following a legislator's version of the Hippocratic Oath, it is important – at least in Lilly's view – for Congress to do no harm in addressing the issue of which reforms will further encourage innovation.

Why, then, does a pharma industry executive come today to call for patents reforms – and do so with a sense of urgency?

I do so for one reason. The United States has enjoyed, as Director Dudas noted earlier today, a unitary patent system that has endured for 215 years – since the 1790 Patent Act. It has provided patent protection in a non-discriminatory manner across the full spectrum of the "useful arts." Its strength has lain both in this unitary character – one patent system serving all inventors – and in its adaptability within unified concepts for patentability common to all technical fields of endeavor.

When the National Research Council of the National Academies concluded its five-year study of the patent system, its first recommendation was to preserve these twin



characteristics of unity and adaptability.¹ However, for a unitary patent system to effectively work across the useful arts, its strengths must outweigh its weaknesses from the vantage point of the full spectrum of users of the patent system. Equally importantly, the patent system must work well not just for inventors and other patent owners, but for those seeking to challenge patents. The patent system is and always has been one where its fairness and its balance have been its sustaining strength.

Is the patent system as it works today meeting the needs that a unitary patent system must meet across the constituencies that it must satisfy? My answer to this question is a simple, “no.” The deficiencies in the current patent system today may diminish its value to the pharma and biotech industries, but they by no means even begin to outweigh the value that these systems bring to our innovation-driven business model.

For other constituencies, this same equation has seen its balance begin to move towards the other side – costs and burdens of the patent system, particularly those imposed in the litigation context, threaten to outweigh the benefits and advantages of the system. Reforms are needed for the patent system to return to the historic balance.

Failure of Congress to act now – when its actions can be more proactive than reactive – may lead to a pair of undesirable consequences. First, it may put at risk the national consensus that strong IP protection – both in the United States and elsewhere – is of paramount importance to our national prosperity. For more than two decades this consensus has driven both domestic and foreign policies and produced an era of innovation and prosperity unparalleled in our history.

Second, absent reforms, some promising enterprises and entrepreneurs, who should be beneficiaries of strong IP laws, will instead find themselves victims of delays, costs, uncertainties, and unpredictability in our patent laws. When valid patent rights cannot be timely secured or invalid patents cannot be expeditiously quashed, the patent right may operate, not as an incentive to innovation, but as a disincentive to investment in new technology.

What reforms now? I will try to define a roadmap based upon my experience that Congress may wish to consider in navigating through the thicket of ideas for reform that has recently emerged.

There will be a common set of themes in my effort at navigation. What can make the patent laws simpler? What can shorten the time it takes to determine what can be patented and what cannot? What can make the patent system operate with greater

¹ “Preserve an open-ended, unitary, flexible patent system. The system should remain open to new technologies and the features that allow somewhat different treatment of different technologies should be preserved without formalizing different standards, for example, in statutes that would be exceedingly difficult to draft appropriately, difficult to change if found to be antiquated or inappropriate, and at odds with U.S. international commitments.” NRC Report, p. 8.



predictability? How can costs in the operation of the current patent system – whether costs in getting patents, enforcing patents, or challenging patents – be remarkably reduced? In this navigation process, I will attempt to outline where we see the hallmarks of fairness and balance guiding choices for patent reform.

Finally, I will try to focus intently on two aspects of the reform process that are of critical importance to its legislative fate. What is ripe for reform, that is, where have ideas for reform matured into viable and well-developed proposals? What ideas have garnered the consensus needed to support moving ahead with reform?

This last inquiry is the one of paramount importance to the pharma and biotechnology industries. Since our industry, more than most others, could continue to prosper or might quickly perish depending upon the content of any basket of changes to the patent laws, we feel that the reform process must understand our needs with particular clarity. I will hope to offer some of that clarity in an issue-by-issue analysis.

Start the Reform Process by Adopting the Consensus Position on the “First-Inventor-to-File” Principle

I would like to start the issue-by-issue approach with the issue that I hope is most ripe and where the consensus for moving forward is most well developed. In a pleasant coincidence, it is also an area that epitomizes how constructive reforms can greatly improve the cost-benefit analysis of the patent system across all constituencies.

One way in which the Congress could significantly simplify the patent laws, provide fairer outcomes for inventors, speed final determinations of patentability and reduce overall costs for procuring patents would be through the adoption of the first-inventor-to-file principle. There was a time not long ago when this suggestion would have provoked a firestorm of controversy, especially among the independent inventor community. Indeed, there was a time when the leading IP organizations in the United States were hopelessly divided on this issue. Finally, there was a time when this issue was raised only in the context of some far-off agreement on international patent harmonization and, even then, only as a “bargaining chip” that we might play in order to extract concessions from foreign governments.

In each of these respects, times and circumstances have changed. Based on the changes during the last decade, it is now abundantly clear that the time for congressional action on a first-inventor-to-file law has come. Allow me to address circumstances and timing issues one at a time.

- On the issue of independent inventor support for first-inventor-to-file reforms, the data are now in that make a compelling case for moving forward now with the reforms. Attached to my testimony is an article by former Commissioner of Patents Gerry Mossinghoff that demonstrates convincingly that the independent inventor community is losing patents – and losing them at an accelerating pace – because of our current law that fails to guarantee the right to patent to the first



inventor to file for a patent. Given the growing costs for securing a patent for any inventor not the first to file for a patent and the 1994 change to U.S. law that puts foreign-based inventors on an equal footing with U.S. based inventors (and will increasingly cost U.S.-based inventors patents that formerly would have been theirs), the disadvantages of our existing law to independent inventor community will only worsen. While I would not presume to speak for the independent inventor community, it would not be surprising to see independent inventors rally around this issue for the same reasons that other inventor groups have traditionally felt that this change in law might be beneficial.

- On the issue of divisions within the broader IP community, a host of U.S.-based organizations have agreed on the future that U.S. patent law should now take. A year ago, the National Research Council of the National Academies, after a five-year study of the U.S. patent system, called for adoption of a first-inventor-to-file rule as part of sweeping reforms to the U.S. patent system needed to prepare it for the 21st century. Earlier this year, the American Bar Association, a one-time opponent of the adoption of this principle as part of U.S. patent law, took a decisive position favoring adoption of a first-inventor-to-file system – with or without a patent harmonization agreement. Only last week, the following statements were offered in support of enactment of a first-inventor-to-file rule during congressional testimony on patent reform:
 - The ABA stated that, in the context of the many proposals for patent reform, Congress should “[a]dopt first-inventor-to-file rule as the centerpiece of reform efforts.”
 - The Business Software Alliance confirmed again its support for adoption of the first-inventor-to-file principle by urging “Congress to take an approach towards harmonization that brings the United States into alignment with other countries’ laws.”
 - Intellectual Property Owners Association stated that “IPO supports first-inventor-to-file because it is the best system for the U.S.”
 - Finally, the American Intellectual Property Law Association is here today testifying on this subject and will again reiterate its support for adoption of the first-inventor-to-file principle.

I would particularly like to support the very specific AIPLA proposals for moving to a first-inventor to file system. They have gone the extra mile to addressing independent inventor concerns. AIPLA proposals would preserve a one-year grace period for the inventor who has disclosed the invention before seeking a patent. They protect an inventor’s earlier patent applications from being used to stop an inventor from filing for patents on later refinements or improvements of the invention. Finally, they would change the patent law very explicitly to state that the right to seek and obtain a patent is the right of the inventor.



The time is ripe for this reform – the consensus for moving forward appears to be in place. We urge that adoption of the first-inventor-to-file principle serve as the centerpiece reform for making our patent laws operate more effectively and efficiently. It would facilitate making other reforms, especially the efforts to create a 9-month window for permitting a post-grant challenge to an issued patent.

Implement the “First-Inventor-to-File” Principle Using the Consensus Views on “Best Practices” for Defining Conditions for Patentability

As we have listened to various constituencies discuss how best to implement a first-inventor-to-file principle, we believe that we are hearing near unanimity on a host of key issues that must be addressed by Congress as we move from one system to another. A collection of U.S.-based organizations has weighed into the debate on the details of implementing a first-inventor-to-file system during the last four years. What has emerged since 2001 is a detailed portrait on how to best construct a set of rules on what should or should not constitute “prior art” (*i.e.*, the information made known to the public before a patent is sought that can be used to determine if a claimed invention is novel and non-obvious), as well as related tests for assessing whether an invention can be validly patented or not.

The “best practices” that have emerged from this exercise include maintaining essentially all of the key features of the patent law that have protected inventors seeking to patent truly novel and innovative subject matter and have protected the public against sweeping into a patent any subject matter that was already known or merely obvious from what was already known.

In a very significant respect, however, these “best practices” for defining prior art will expand subject matter that can qualify as prior art and, in doing so, potentially diminish to some degree what subject matter can be validly patented. Heretofore our patent laws have recognized that knowledge of an invention represented prior art only if the knowledge came from a patent or a publication or, if not found in a patent or a publication, must be shown to have been in existence *in the United States*. This type of unpublished knowledge, if it existed only elsewhere in the world – even if readily accessible to the public elsewhere in the world – could not qualify as prior art to deny a patent.

The “best practices” approach potentially expands the knowledge that can defeat the ability to patent an invention to anything that is known anywhere in the world. While this change may make it more difficult for some inventors to be awarded some patents, Lilly views this as the right choice. We fully support considering global knowledge of an invention in order to determine whether a U.S. patent for the invention should validly issue. Even if the current U.S.-based limitation on prior art can be justified on policy grounds, the emergence of the Internet and the other capabilities of the information age have made geographic limitations on prior art more problematic and less desirable.



The geographic expansion of unpublished “knowledge” as prior art does, however, raise a very important issue. Any new provisions in the patent statute implementing this change must be unmistakably clear as to what now will and what will not qualify as prior art.

Unpublished foreign “knowledge” should not qualify as prior art to an invention unless it meets the same requirements for accessibility that have long applied when unpublished knowledge in the United States was determined to qualify as prior art. Under U.S. patent law today, only unpublished knowledge that has become reasonably and effectively accessible to persons skilled in the technology to which the invention relates could so qualify.

Lilly notes that the “best practices” consensus view on defining what knowledge can qualify as prior art do not intend either to raise or to lower the existing public accessibility hurdle for qualification as prior art. As Congress changes to a global definition for this type of prior art, the definition should be in the statute and explicit – but not otherwise diminish or expand the qualifications for unpublished or knowledge-based prior art.

A “best practices” patent statute should make clear that knowledge of an invention can arise from its sale or other use, just as current law provides.² Further, knowledge can arise based upon whatever can be comprehended by persons skilled in the area of technology from any subject matter that is thereby made publicly accessible, precisely in accord with existing patent law principles. Equally importantly, knowledge can be either express or inherent and any action by Congress should make clear that inherent knowledge arising from subject matter that has become publicly accessible bars a later patent on anything thereby made inherently known.³

² AIPLA has proposed – and Lilly supports – elimination of the so-called “forfeiture” aspect of the current patent law that prevents inventors (and *only the inventors*) from patenting subject matter that they themselves have placed or caused to be placed into non-public commercial use or made the subject of non-public offers for sale. Where an inventor has otherwise placed an invention in public use or on sale, including made offers for sale, it is clear that both the inventor (unless the inventor sought a patent before the end of the 1-year “grace period”) and any third parties ought to be barred from patenting such an invention. While this forfeiture provision makes sense under our current patent law, it is unnecessary, if not counterproductive, once a first-inventor-to-file rule is adopted. Under our current law, the forfeiture provision assists in securing that an inventor cannot wait to file for a patent until another inventor seeks a patent and then assert the right to patent the invention based upon an earlier date of invention. In a first-inventor-to-file system, this possibility does not exist.

³ By way of a simple example of what “inherent knowledge” means, if aspirin is sold for treating a headache and, subsequently, a later inventor attempts to patent the discovery of a method for treating headache through administration of a medicine that inhibits a COX enzyme, any patent that issues for this invention will be invalid if it can be shown that an

The underlying requirement for “public accessibility” should apply regardless of the nature of the disclosure that is alleged to represent prior art. Thus, a disclosure based upon a use or other unpublished knowledge of the invention should be treated no differently from a disclosure appearing in a purported “printed publication” in assessing whether the requirement for public accessibility has been met. The courts have applied – and should continue to apply – the same “public accessibility” framework for assessing the prior art status to determining whether a disclosure of subject matter qualifies as prior art irrespective of the nature of the disclosure. “The statutory language, ‘known or used ...’ (35 U.S.C. §102(a)), means knowledge or use which is accessible to the public.” See *Carella v. Starlight Archery*, 804 F2d 135 (Fed. Cir. 1986). “Thus, throughout our case law, public accessibility has been the criterion by which a prior art reference will be judged for the purposes of [35 U.S.C.]§ 102(b). Oftentimes courts have found it helpful to rely on distribution and indexing as proxies for public accessibility [in the case of an alleged printed publication]. But when they have done so, it has not been to the exclusion of all other measures of public accessibility. In other words, distribution and indexing are not the only factors to be considered in a § 102(b) ‘printed publication’ inquiry.” *In re Klopfenstein*, App. No. 03-1583 (Fed. Cir.), slip op. August 18, 2004.

Again, because of the new global reach of all forms of prior art under a “best practices” approach, Congress should undertake an explicit codification of the long-recognized “public accessibility” criteria and, as noted above, break these criteria into their two established components, one relating to the *reasonableness* of the required efforts to secure access to the disclosure (*i.e.*, a test to determine the extent to which the alleged public knowledge is capable of being physically located) and a second relating to the intellectual *effectiveness* of the access (*i.e.*, a test to determine whether the alleged public knowledge is capable of being understood by a human being). These two components arise from longstanding judicial precedent.

The gist of the public accessibility criteria based upon these two components was described through a five-part analytical paradigm in *Philips Electronic and Pharmaceutical Industries Corp. v. Thermal and Electronics Industries, Inc.* 450 F2d 1164 (3rd Cir. 1971), as applied to a purported printed publication. “[A] proponent of a microfilm as a ‘printed publication’ under the statute should produce sufficient proof of its dissemination or that it has otherwise been made available and [1] *accessible to persons concerned with the art to which the document relates* and thus most likely to avail themselves of its contents. He should be able to make a satisfactory showing that a person interested in and [2] *ordinarily skilled in the art* [3] *can locate it*, and [4] *understand the essentials of the claimed invention* [5] without further research or experimentation.” *Emphasis added.*

inherent property or characteristic of aspirin in treating headache was the inhibition of the COX enzyme.

As to element four of this five-part analysis, the “effective accessibility” component, the Court of Customs and Patent Appeals has cogently noted the basis for *effective accessibility* component (as distinct from the requirement for reasonable accessibility in the sense of physical access), stating that, “if the publication [asserted to be prior art] were illegible, whether ‘printed’ or handwritten, no one would argue that it would constitute a statutory bar” *i.e.*, a basis for denying a patent for an invention. See *In re Tenney*, 254 F.2d 619 (C.C.P.A. 1958).

Moreover, as is clear from the *Philips* decision, these components are to be objectively applied, *i.e.*, the reference point employed for assessing the accessibility criteria is the hypothetical person of ordinary skill in the art to which the claimed invention pertains. This objective focus is intended to assure that the criteria for assessing public accessibility do not turn on whether information was disclosed to the inventor – or whether the inventor was entirely ignorant of such information.

A congressionally codified standard should incorporate the same general – and objective – five part analytical paradigm used in the *Philips* decision. However, on the fifth of the five criteria in *Philips*, it would be appropriate to refine the level of permissible effort set out in the *Philips* decision (*i.e.*, the passage in *Philips* referencing the standard, “without further research or experimentation”). We would support an “undue efforts” principle. The “undue efforts” standard would be intended to allow subject matter that can be accessed without undue effort to qualify as prior art. This standard could be applied analogously to the “undue experimentation” standard that has been used in assessing the enablement of a claimed invention under 35 U.S.C. §112, first paragraph. Thus, the “undue effort” standard could draw a clear distinction between (1) knowledge that, while not categorically secret, is insufficiently accessible to be regarded as public and (2) knowledge that, because of its sufficient accessibility, can advance progress in the useful arts to which it relates.

We would further urge that Congress expressly reject the concept applied in some foreign patent systems that *any* non-confidential disclosure of the invention is sufficient to create prior art as to the subject matter that is non-confidentially disclosed. Indeed, it is appropriate to require something more than a mere reasonable possibility that persons of ordinary skill in the art could achieve meaningful access to a disclosure.

Lilly realizes the importance of making these “best practices” changes with extreme care. With any legislation, there is a risk of unintended consequences. By codifying existing principles for determining prior art as part of the expansion of the definition to include foreign knowledge of an invention, Congress can assure that it is not otherwise making changes that go beyond what is needed to normalize our laws with those of other countries under the “best practices framework.”

In doing so, Congress can make clear that any statutory changes that are made do not call in to question decades of established case law on prior art, including the cases previously cited. It is vitally important, therefore, to tie statutory changes to the language from decades of case law both in statutory language and appropriate legislative history.



By doing so, Congress can avoid spurring unnecessary litigation that can otherwise result from reformulated standards of prior art.

Specifically, Congress needs to exercise the greatest care to assure that subject matter that was already being used and commercialized within the United States that would not be patentable by a third party today does not become patentable under a “best practices” formulation of the patent law.

For all these reasons, we are particularly supportive of the AIPLA’s detailed proposal that proposes to codify what the courts have decreed is the inquiry mandated under the current “known or used” and “in public use” standards, *i.e.*, whether subject matter was “readily and effectively accessible.” This standard, as we understand it, contemplates that subject matter, once widely deployed, will be available as prior art, both for what is expressly used or otherwise known and for what inherent knowledge is created.

In summary, Lilly encourages Congress to take an approach towards harmonization that brings the United States into alignment with certain aspects of other countries’ laws without, however, diminishing or expanding the scope of existing prior art (other than the expansion inherent in the removal of geographic limitations on unpublished knowledge). This can be done by carefully crafting the standard along existing patent law principles for defining what is and is not publicly available. Carefully legislating, such as AIPLA has proposed to in its “best practices” implementation, should preclude the otherwise serious concerns over unintended gamesmanship of patenting concepts already in deployment commercially – whether in the United States or elsewhere.

Stop the “Inequitable Conduct” Defense From Crippling the Effectiveness of the “Duty of Candor” by Adopting AIPLA and ABA IPL Section Reforms

Since 1979 – the patent office has had a very explicit “duty of candor and good faith” in its rules designed to assure that patent examiners get all the information they need to make the right decisions in deciding whether to allow a patent to issue.⁴ The office undertook a major effort in the early 1990s to retool the duty to make certain that it was fully comprehensive with the needs of patent examiners. The only meaningful

⁴ Patent applicants in the United States face a unique requirement that other patent systems outside the United States do not impose: they are obligated under the “duty of candor and good faith” to refrain from misrepresenting information and to affirmatively disclose all information of known materiality to the patent examiner. As we look to greater international harmonization of patenting processes, Lilly would urge the Congress effort to reaffirm the role of duty of candor, actually give the patent office greater statutory authority to manage and strengthen the duty, and make clear that a duty of candor should play a central role in fostering the integrity of the U.S. patent system irrespective of other efforts at pursuing more harmonized approaches to patenting.



enforcement of the duty of candor today is in the courts in the context of patent infringement litigation, where violation of the duty of candor with the intent to deceive the patent examiner automatically renders the patent permanently unenforceable.

Despite decades of work at perfecting the duty of candor and good faith, Director Dudas appeared today to lament the need for “increased applicant responsibility” as he termed it. He cited a common concern among those within the patent office: *“Applications filed with large numbers of prior art references, without any guidance as to which references the applicants believes to be most relevant, have an impact on efficient examination.”*

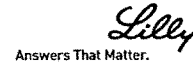
The root cause of the problems that the patent office today faces with deriving the expected value from the duty of candor does not lie in deficient patent office rules. The problem is not that the patent office has not set the standard for conduct high enough. It is not that patent applicants are unwilling to act with full and complete candor in dealings with the patent office. As Lilly assess the current dilemma, the root cause lies rather in the perverse incentives that are created because of the manner in which the “inequitable conduct” defense is applied in the courts. Applicants getting patents need to act defensively – in order to blunt the “inequitable conduct” charges that are almost inevitably leveled once the patent is litigated.

Even though the “inequitable conduct” defense undeniably operates as an incentive for patent applicants to make the fullest imaginable disclosure of information to the patent office, it has a glaring deficiency. The “inequitable defense” provides no incentive for patent applicants to work with patent examiners to secure the issuance of a completely valid patent. Completely valid patents are the target of “inequitable conduct” charges with the same frequency as patent containing invalid claims.

Instead of creating an incentive to procure entirely valid patents, the “inequitable conduct” defense encourages patent applicants to do exactly what Director Dudas finds to problematic – *submit large numbers of prior art references without any guidance as to relevance or content*. In short, to blunt later charges of concealment of known information, patent applicants are forced to make the work of the patent examiner more difficult, not more efficient or accurate.

We have seen one proposal that reaffirms the duty of candor and would actual strengthen the duty and the authority of the patent office to mold and reinforce. This proposal, authored by the AIPLA, further operates to address the chief deficiency with the “inequitable conduct” defense. The AIPLA proposal would provide an incentive to obtain a wholly valid patent – and an incentive to work with the patent examiner to see that was done. We would urge Congress to give it careful consideration.

The proposal of AIPLA, which is quite similar to a parallel position of the ABA IPL Section, provides this incentive in an utterly simple and elegant fashion – do not allow the defense of inequitable conduct to be pled in a case where the patent at issue is entirely valid. In such a case where no actual fraud can exist because only a wholly valid



property right was secured, it makes sense that any issue of possible misconduct that did not go to the validity of the issued patent be addressed by some means other than a mandatory holding that the wholly valid patent be rendered permanently unenforceable.

Lilly views this as a policy-driven, common sense way of reining in the “inequitable conduct” defense and eliminating the perverse aspects of its application. The primary incentive of the patent applicant would be aligned with that of the underlying rationale for the duty of candor. The best defense to a possible “inequitable conduct” charge would be to work closely with the patent examiner to assure that the examiner made the right decision and the patent that issues is entirely valid.

If Congress were to make this change in the operation of the “inequitable conduct” defense, Director Dudas would find more responsiveness than resistance to his agenda for increased applicant responsibility. With this reform to inequitable conduct law, Lilly believes that it would be joined by others in the patent procuring community in supporting the vision of Director Dudas that the patent examiners be given the best possible information from which to make the best possible decisions on whether to grant patent claims. Indeed, the individuals who have expressed to Congress the need for the greatest caution in proceeding with inequitable conduct reforms should be the most supportive of the AIPLA and ABA IPL Section proposals for inequitable conduct reform.

Reform to the “inequitable conduct” defense should in our view be made a top congressional priority. It inflicts outrageous costs on the patent system. Moreover, there is only the meager evidence that the defense has served any meaningful deterrent value proportionate to that cost.

The costs to the patent system are huge because the “inequitable conduct” defense rears its head in virtually *every* important patent case. Since the penalty of permanent enforceability of the patent affords the opportunity for sudden victory for an accused patent infringer – even if the patent is otherwise entirely valid and unquestionably infringed – it is almost an irresistible defense whenever even the slightest possible infraction of the duty of candor might appear to exist.

Had it served its role as an effective deterrent to misconduct, it presumably would mean that inequitable conduct itself would be a truly rare event and, given the care with which patent applicants knowing of the duty and of the defense would conduct themselves, it would be expected to arise with great infrequency in patent litigation. The disconnect between its presumed role as an effective deterrent to bad conduct and its presence in virtually every important patent litigation should tell the whole story of the need for action by Congress.

AIPLA has made proposals that, if Congress were to adopt them, would actually strengthen the threat of severe sanctions for misconduct. One of the core problems today with the law on “inequitable conduct” is that, whatever the crime, the punishment is the patent “death penalty” – holding the entire patent permanently unenforceable. The reform proposals made by AIPLA would maintain the patent “death penalty” for truly



capital offenses – those involving misconduct that led the patent examiner to issue a patent with invalid claims – but create new mechanisms that allow serious, but lesser sanctions to be meted out for an array of lesser acts of misconduct. Instead of the situation today where “inequitable conduct” allegations pollute every major patent litigation, but almost no patents are ever found unenforceable, the AIPLA proposal would create the prospect of serious sanctions being meted out in cases where courts are justifiably reluctant to impose the “death penalty.”

Some advocates of patent reform have expressed concerns that Congress not touch this issue because of the perception that we live in an era where companies should be held to higher standards of accountability and transparency and any effort to limit the “inequitable conduct” defense might be seen as diminishing accountability. These are legitimate concerns. Congress needs to act with extreme care as it moves forward with reform in this area.

That said, we believe that, as the AIPLA proposals are more carefully examined, they will more than adequately address such concerns. Because the AIPLA proposals align the incentives of applicant and patent examiners in obtaining wholly valid patents and would actually impose new sanctions and accountability, they should raise – not lower – the bar on the integrity of the patent examination process.

If a Consensus Can Emerge on a Fair and Balanced Reform Proposal, Open a 9-Month Window for a Post-Grant Opposition to a Patent

Experience would suggest that opening a window after a patent is granted to permit members of the public to oppose a patent in the patent office may create more issues for a patent system than it solves. In no country of the world are such administrative post-grant procedures conducted inexpensively, rapidly, and with the highest standards of fairness to the patent owner. A substantial collection of issues must be carefully titrated to make certain that the procedure is fair to the patent owner, while providing a meaningful opportunity for an opposer to correct errors made by the patent office.

A post-grant opposition, if it is to afford the opposer a meaningful forum for opposing a patent, cannot come cheap. As with most contested proceedings, the parties involved can expect to generate legal bills in the tens to hundreds of thousands of dollars.

Most importantly, protections for the patent owner in a district court litigation will be stripped away to the extent that discovery is limited compared to what a court might afford. Let me offer a real-life Lilly example. Three generic companies attacked the validity of the one patent that protects our \$4 billion medicine, Zyprexa. They claimed that the examiner should not have relied on evidence of non-obviousness submitted by Lilly, which had taken the form of standard toxicology testing that Lilly had conducted to provide evidence of non-obviousness.



Through discovery in the courts, we were able to learn that the attack on the validity of our patent was without any conceivable merit. The generic drug companies that questioned the validity of our evidence of non-obviousness had actually repeated the testing we had done and completely confirmed the results that we had reported to the patent examiner.

An opposition proceeding that does not allow the patent owner to be assured that the opposer is presenting the *whole truth* to the patent office could have made Lilly's defense of its patent more difficult. A patent owner should not be faced with potentially losing a patent in such an administrative proceeding that would be very easy to defend given the many protections available to litigants in a court.

Finally, the patent owner can face the equivalent of "double jeopardy" if patent validity and enforceability can be litigated a second time in the courts after the patent owner has survived an opposition. Treating the patent owner fairly raises the issue of what estoppel provisions ought to exist.

So where is Lilly on this issue? First and foremost, we are not eager to see Congress move forward on any proposal for post-grant opposition until the time is ripe for doing so. There are 100 ways of getting a post-grant opposition system wrong for every way forward to a fair and balanced post-grant opposition regime. At this juncture, there is a cacophony of voices with differing visions of what a post-grant opposition should look like. This alone is a reason for Congress to move carefully and deliberately. This is an issue where we know the devils lie in details, even apparently minor ones.

We are most alarmed – and alarmed is not a word I use lightly – by proposals that allow post-grant oppositions after the 9-month window after a patent issues. The 9-month period is critical for any number of reasons. First and foremost, a patent owner should be subject to a post-grant opposition only once. If there is to be an open hunting season targeting issued patents, patent owners have a right to insist upon quiet title once an opposition period has expired. If there is to be only one post-grant opposition against a patent, it cannot feasibly start until the window for all opposers to file their oppositions closes.

This makes the 9-month period virtually ideal. The patent owner only has a limited "hunting season." A single opposition can start and finish within a couple years after the patent has issued. There can be a quiet title.

Most importantly, a limited opposition period has the advantage of changing behavior for members of the public. Big businesses, which are likely to file most of the patent oppositions, will be forced into diligent behavior to examine patents as they issue and determine when an issued patent merits an opposition. It will force early challenges to patents that will serve to remove invalid patent claims promptly.

If these same big businesses can hold back – because they can make use of the same opportunity for an opposition in the patent office years later, once threatened with a



lawsuit – the public will face the consequences of dealing with an invalid patent for years and years. The prime virtue of the 9-month window is the incentive to investigate issued patents and promptly act to eliminate invalid ones.

This brings me back to the pharma and biotechnology industries and the vast value that a patent has in our industry by the time a patented medicine reaches the market. Lilly lost a patent in 2001 that was otherwise set to expire in 2004. The day the court decided that our patent was not valid, the market capitalization of our company *declined* in value by an amount equal to the entire market capitalization of General Motors that day. One patent and three lost years of patent life.

There is no fair way to have patents of enormous commercial importance opposed in the patent office without the strongest possible due process protections. Tuning a provision for a 9-month post-grant period is one enormous challenge to get just right; creating an administrative revocation provision that might operate at any time during the life of a patent presents insuperable problems for the pharma and biotechnology industries.

A last consideration needs to be raised – and it is by no measure the least of Lilly's concerns. The idea of a post-grant opposition proceeding in the patent office that would operate as a true *inter partes* procedure means creating new capabilities within the patent office that do not exist today and having the patent office operate such an *inter partes* proceeding with an unprecedented level of quality, promptness, and efficiency and accuracy. The closest analogue that exists today to the post-grant opposition is the *inter partes* patent interference proceeding. Few who have lived through patent interference proceeding believe it is a foregone conclusion that the patent office will be able to efficiently and effectively conduct post-grant oppositions without an enormous effort to build capabilities and capacity.

Unleashing an unproven procedure conducted by an administrative agency with no proven track record of success with *inter partes* contests is at best an experiment. The experiment should begin where its policy justification is strongest – during the 9-month post-grant window.

Lilly does support post-grant oppositions – if they can be done right. Besides the 9-month window, there are other aspects of the post-grant opposition proposals that we believe are crucial.

We believe that the first predicate for effectively operating a post-grant opposition is simplifying the patent law. If the United States creates a post-grant opposition window without further changes to its patent law, it will be the only country in the world that has attempted this feat under a first-to-invent regime. The first-to-invent principle means that a patent owner can seek to evade much prior art by seeking to establish an early invention date. These can be complicated demonstrations of when an invention was conceived and the diligence that was used in actually reducing the conception to a tangible, physical embodiment. When these proofs are offered, an opposer must be in a position to cross-



examine and rebut these showings – if the opposition is going to allow a full and fair opportunity to oppose the patent.

Lilly would urge Congress to first implement the first-inventor-to-file principle and only then to authorize oppositions for patents that have been examined and issued under this principle. These opposition proceedings will depend for determining what is prior art on two objective factors: when the patent was filed and when the asserted prior art became publicly accessible. Neither of these inquiries requires for a full and fair opposition that *any* discovery from the inventor or patent owner be forthcoming.

As a second matter, Lilly would urge Congress to precede or accompany adoption of a post-grant opposition system with fundamental reforms to the law on inequitable conduct. The duty of candor and good faith has served the patent system well. It *must* apply to post-grant opposition proceedings. In applying to post-grant oppositions, it must equally apply to opposers and to patent owners – both must be subject to sanctions sufficient to deter misconduct.

Without Congressional intervention, there is no effective mechanism to hold an opposer accountable for misconduct before the USPTO. Congress should create one.

Further, post-grant opposition will burden patent owners in later litigation with a plague of new allegations of inequitable conduct. While inequitable conduct reform is critically important with or without post-grant opposition reforms, Lilly sees the introduction of a post-grant opposition law as a compelling reason to institute needed reforms.

If a Post-Grant Opposition System is Instituted, Provide an Enhanced Pre-Grant Mechanism for Third Party Submissions of Prior Art

A post-grant opposition system, properly implemented, provides yet another incentive for a patent applicant to assure that the patent examiner made a full and complete consideration of all relevant prior art and made an accurate determination of patentability. Doing so will make it far less likely that some omission or oversight in the prosecution record of the patent will open the door to a post-grant opposition. Given that the opposition will likely have a threshold standard that must be met by the opposer before the opposition can be instituted, patent applicants will be greatly advantaged if no substantial question of patentability remains once the patent is granted and/or an opposition request otherwise cannot demonstrate a substantial basis for opposition.

In the event of a post-grant opposition proceeding with a suitable threshold, it is particularly desirable, therefore, for patent owners to gain early access to *all* the prior art – and any discussion of the relevance of the prior art – that might otherwise first appear in an opposition. A patent owner that first faces these issues after the patent is granted is necessarily constrained by the time limits for action during a post-grant opposition and by the limits that might be imposed on amending claims.



Thus, Lilly believes that Congress should consider the issue of pre-grant submissions of information together with post-grant opposition provisions. In doing so, full account should be taken of not only the benefits to the patent owner, but also the benefits to the public if more accurate and complete examination is the result.

Nothing in this endorsement of pre-grant submission of prior art together with the submission of a concise description of the relevance of the prior art should be construed as an endorsement by Lilly of any form of pre-grant opposition. Congress wisely chose to add to the patent statute a part of the American Inventors Protection Act a prohibition on pre-grant opposition. In making any changes on pre-grant submission of prior art that might prove desirable, Congress should leave unaffected the statutory prohibition on pre-grant opposition proceedings.

Do Not Change the Burden of Proof in Patent Litigation

Several recommendations have emerged for changing the burden of proof in patent litigation. For the pharma and biotechnology industries, these proposals would profoundly and negatively affect the course of our businesses. We are routinely forced under provisions of Hatch-Waxman to litigate patents on which we have invested billions of dollars based on the presumption of their validity and the difficulty of overturning that presumption. If for no other reason than changing the burden of persuasion might change the perception that the patents on our medicines were less reliable, we would oppose this change.

The increased business risks that would flow from even a potential decrease in the reliability of a patent on a new medicine could quickly translate into a diminished willingness to invest in its creation.

Some proposals for changing the burden of proof have been straightforward. The FTC report simply sought a “preponderance of the evidence” test be applied across the board. A more complicated proposal from the Business Software Alliance would lead to more complexity and uncertainty in its application, forcing an entire new field of patent litigation – litigation over the applicable standard of proof.

Lilly believes that sustaining a “clear and convincing” evidence standard of proof – when coupled with other possible patent law reforms – makes impeccably good policy sense. First, if a new opportunity for post-grant opposition is created, we believe that it could be crafted in a fair and balanced fashion, possibly using a “preponderance of the evidence” standard. This would provide a very significant incentive for challenges to use the opposition procedure and, if a patent is invalid, have it quickly eliminated. If the same relaxed standard of proof is available later, the incentive to act early – and in the public interest – to eliminate the patent is greatly lessened.

Second, we truly believe in a patent system that rigorously applies that criteria for patentability – in the initial examination and in the post-grant opposition proceeding – and then affords the patent owner and the public the highest possible degree of certainty



that the patents that remain standing after the opposition opportunity has run its course are patents of certain validity. The “clear and convincing evidence” standard plays an important role here in underscoring that public policy.

Do Not Curb Abuses Arising From “Continuing Applications” by Barring Legitimate Efforts to Protect an Invention

A significant area of abuse of the patent system today arises from the unlimited ability of an inventor to seek a multiplicity of patents on an invention for the entire 20-year patent term. In fiscal year 2004, Director Dudas has testified that more than 100,000 out of the 355,000 patent applications filed in the United States were so-called “continuing” applications for patent. Imagine the differences in its operations if during the last year the patent office faced a mere 250,000 new patent applications instead of over 350,000 – which might have been the case had continuation applications been abolished.

While I have in the past proposed the complete abolition of continuing applications, there is little, if any, support that I have seen for taking such draconian step. Equally significantly, there is no likelihood of a consensus developing that this reform represents a viable, much less a complete approach to address the potential for continuing application abuses.

Lilly agrees fully with Director Dudas that “it is necessary and appropriate for all to consider whether some restrictions should be placed upon so-called ‘continuation’ practices.” Indeed, we at Lilly would go farther and suggest that this issue is an urgent one for Congress to address.

Unfortunately, we have yet to see a proposal that we can support and have none to suggest or propose to Congress at this time. We applaud the efforts of the only organization to step forward with a proposal to address these abuses, the Business Software Alliance. However, their proposal is so draconian and punitive that it is unlikely to be regarded by many constituencies as a good-faith effort to address a serious issue.

Sadly, this may be a needed area for reform that may not be ready for action in this Congress. The constituencies that need to come together to tailor a fair and balanced proposal that targets abuses and spares legitimate efforts to fully protect inventions appear to have much work left undone.

Limit Assertions of “Willful Infringement” That Can Operate to Discourage Patent Challenges Having Substantial Merit

The NCR made a seminal contribution to the debate over patent reform by noting that much of what is wrong with the enforcement of patents can be traced to the prevalence of so-called “subjective elements” in patent litigation. These are the “inequitable conduct” defense, the “best mode” requirement, and allegations of “willful



infringement.” All depend upon ascertaining the actual state of mind of one or more individuals at a relevant date – often a distant date years in the past – on issues requiring complicated judgments. Was information known; was it material; was it known to be material; was a non-disclosure of known information of known materiality with an intent to deceive? What constitutes a mode of carrying out an invention; was one mode thought by the inventor when the patent was filed to be better than the rest; were sufficient details of such a best mode sufficiently revealed in the patent? Did the infringer know of the patent and its possible infringement; did the infringer nonetheless hold a reasonably held belief that the patent might be held invalid, unenforceable or not infringed?

At least from Lilly’s perspective, a convincing case has been made that simply eliminating the “best mode” requirement from the patent statute is appropriate, largely because the public interest in having complete patent disclosures can be achieved through vigorous application of the requirements that the claimed invention be fully described in the patent and all the information needed to carry out the full scope of the invention be likewise present in the patent.

Similarly, as previously discussed, the “inequitable conduct” defense should remain, but its application tempered by eliminating its application where the inventor has procured a completely valid patent, thus providing an incentive for doing so that might enhance the operation of the duty of candor and good faith, not diminish it.

On the third of the NRC proposals for reforms to “subjective elements,” Lilly would urge that significant reforms must likewise be considered. Unlike the consensus that appears to be emerging on “best mode” and “inequitable conduct” – where both AIPLA and the ABA IPL Section support similar approaches to reform – there appears to be less consensus on how much or how little to whack away from the law on willfulness. Our hope, however, is that this lack of consensus is a temporary phenomenon and that interested groups can identify reform proposals that strike just the right balance.

In a comprehensive reform of all three of the triad of “subjective elements,” Lilly has yet to see a proposal for reform that it would actively oppose. Without favoring any one approach over another, allow me to suggest one approach that mirrors the approach to “inequitable conduct” reform.

In the case of “inequitable conduct” reform, there is a threshold that we support that is clearly policy-driven. To have an incentive for inventors to seek and obtain only valid patents, the “inequitable conduct” defense should be prohibited unless and until it is determined that one or more claims in the patent has been invalidated. The threshold would, at the time it is crossed, open the door to pleading the defense.

If an analogous approach were taken to reforms to the doctrine of “willful infringement,” Lilly would suggest that the operable policy driver should be to encourage patents of questionable validity to be challenged in the courts – and the specter of multiplied damages based upon a willfulness allegation not serve to dissuade an accused infringer that has developed a substantial defense to the infringement of the patent. A



threshold, therefore, to pleading “willful infringement” might be instituted that would not permit its pleading until a court had determined that there was no such substantial defense that had been presented.

Such a threshold would focus willfulness issues on those cases where an infringer charged with a duty of due care to avoid the infringement *at no time* could have had a reasonably held, good faith belief that it might avoid liability under the patent. Such a rule would unwind the knotty problems of waiver of opinion of counsel where a defense to willfulness was based upon attempted reliance on competent legal advice.

Do Not Force Inventors to Prove Irreparable Harm in Order to Stop Infringement of Valid Patents

There is one issue on which Lilly believes that it can speak for the entire pharma and biotechnology industries. Proposals have recently emerged that would require an inventor to affirmatively prove some irreparable harm in order to stop infringement of a valid patent. Without such affirmative proof, a court would be effectively barred from enjoining the infringement of a valid patent.

We at Lilly have worked hard to understand and, where appropriate, acknowledge the concerns of the proponents of this proposal. We recognize that the proponents may have legitimate concerns that the threat of an injunction after trial – and before an appeal that might succeed to invalidate the patent or establish that the patent was not infringed – may force a business to prematurely settle patent litigation, rather than risk a loss at trial.

In that relatively rare sequence of events, a business may be subject to an injunction being entered that may destroy a market before a successful appeal permits the injunction to be lifted. The specter of this possible outcome is a factor that every company must consider in determining whether or not to settle before the infringement lawsuit ever goes to trial. Most accused infringers have a motivation to do so because they can anticipate having little, if any, meaningful leverage after a trial court defeat.

When such pre-trial settlements are made in situations where bona fide issues continue to exist over whether the patent is valid or actually infringed the public may be the loser because the questionable patent is never actually litigated. Lilly agrees that strong public interests are served when patents of questionable validity and enforceability can be taken to court and, if invalid, removed as obstacles to competition that otherwise would flourish.

It may be that there are ways for Congress to assess the role that the prospect of an errant injunction after trial plays in decisions to prematurely settle this type of litigation rather than take a case to trial. If the substantiality of such concerns can be validated, Lilly would support a careful study of a legislative response that might remove unwarranted disincentives to taking questionable patents to trial in a manner that would serve the public interest.



All that said, we are no less than appalled by a recent proposal for patent reform that – boiled down to its essence – would simply prevent enforcement of a substantial number of valid and infringed patents. The gist of this proposal is to place unprecedented limitations on injunctions for patents that are both valid and infringed as confirmed by a final, non-appealable court judgment. Under the proposal, infringement of such a valid patent could not be stopped where the patent owner could not surmount the additional hurdle of showing some irreparable harm. In a word, this proposal forces a court to recognize a compulsory patent license.⁵

The proposal is a clean brake with over 200 years of respect for patents as property rights. The implications of this proposal can be understood through a simple analogy. You own a weekend home. I decide that I am going to move into your home on weekdays. When you go to court to evict me, I simply rely on the fact that I am a model guest, willing to pay a reasonable rent, and you cannot be even remotely harmed, much less irreparably harmed, because of my presence on your property during the days when you are off living elsewhere.

Just as you would be outraged if a court sustained my right to be a squatter on your property, patent owners who have survived a court challenge, and been confirmed to have valid and enforceable patent rights, cannot be expected to stand by idly for a proposal that would sanction compulsory squatting. Whatever the possible abuses in the current law arising from the potential for an errant post-trial injunction to issue, the proposal to disable the right to enforce patent rights as property rights after a final, non-appealable adjudication of infringement is entirely unacceptable.

I will not further dwell on this proposal, partly on the assumption that the widespread opposition to it will eventually lead the discussion of issues of injunctive relief into more possibly fruitful areas for reform. However, based upon Lilly's understanding of the requirements of U.S. obligations under TRIPs, it is difficult to rationalize the proposal with our treaty obligations.

Lastly, in the pharma industry we are acutely aware that some countries outside the United States are committed to respecting only the most minimalist standards of IP protection guaranteed under TRIPs. The mere fact that the United States Congress might seriously debate a proposal that would eviscerate the right to enforce many valid patents could suggest to some countries that this "no injunction" proposal might pass muster under TRIPs.

⁵ Non-voluntary licensing of validly patented inventions has heretofore been historically disfavored under U.S. patent laws. A free market system, by its very nature, is designed to afford respect for all types of property rights. Chairman Hatch has noted, "As a defender of, and believer in, property rights, including intellectual property rights, I am always leery of systems that impose government-mandated prices, sales or licenses." See http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.View&PressRelease_id=1105&IsTextOnly=1, "Examining the Implications of Drug Importation (July 14, 2004).



Again, we reluctantly conclude that this is an area where, even if the need for reform were to be conceded, we have seen no proposal that is proportionate to any abuse and narrowly tailored to address it. We would urge Congress not to discredit the many good ideas for making needed reforms to the patent system by advancing such a profoundly anti-IP proposal that would prevent courts from stopping infringement of valid patents.

Do Not Limit Any Inventor's Damage Award to Amounts Less Than Adequate to Compensate for the Infringement

Lilly has reviewed a recent patent reform proposal that purports to require courts to apply a new recipe for awarding compensatory damages to a patent owner. We believe that this proposal is deficient on several grounds. It states, "Whenever the invention is ... an approved ... apparatus including within it elements otherwise known in the art, then any award of a reasonable royalty or other damages shall be based only upon such portion of the total value of the ... apparatus as is attributable to the invention alone and shall not include value attributable to ... elements otherwise known in the art"

We have attempted to understand this provision in terms of a simple pharma invention. Our example is the medicine, Vytorin[®] – which is a patented combination of two known medicines, ezetimibe and simvastatin. The two elements of this patented combination are otherwise known in the art. Under the proposed limitation on damages, the value of the two known elements must be expressly excluded from any calculation of damages. After doing so, however, there is nothing left as a basis upon which to measure damages. The proposed amendment to the patent statute operates in this case – and presumably many others – in a determination of damages that are in no way adequate to compensate for the infringement.

We feel that we need to put a stake in the ground on this proposal. Congress should not act to constrain a court – even in a single patent case – from awarding damages in amounts adequate to compensate for infringement. If reforms are needed to the law of patent damages, then Lilly would suggest the following parameters be used to bound this debate:

- Some abuse of the current operation of the patent damages statute be clearly documented. Any proposed reform should target only the abuse and spare the innocent bystander. What is the problem with patent damage awards to be addressed? What are the root causes? What are the overarching policies to be vindicated through a reform?
- Any damages reform effort should start from the premise that every patent owner is entitled to damages adequate to compensate for the infringement; no category, type, class or classification of invention or inventor should get less than an adequate remedy. Indeed, TRIPs should command no less for future patent owners and the Takings Clause should discourage Congress from providing any less for existing patent owners and patent applicants.



- If damages reform is needed, it should be confined to patent owners that might be overcompensated absent the reform, *i.e.*, obtain more than an adequate remedy in the form of compensatory damages. However, to support reforms consistent with this tenet, it is vital to know who such patent owners might be and why the patent law does not now constrain them to only a fair, compensatory award.

Lilly is prepared to support reforms aligned with the tenets above and has an open mind on this topic. Unfortunately, we have no constructive proposals to offer and we have yet to see any proposal that might provide a satisfactory way forward.

Given the gravity of the implications of any attempt to limit the manner in which damages might be determined, it may be that other patent reforms should go forward without addressing this topic given its apparent unripeness and the lack of any consensus.

Do Not Repeal Existing “Off-Shore” Infringement Remedies Absent Some Compelling Policy Basis

Congress may be faced with the calls to limit or eliminate one of the remedial provisions added to the U.S. patent laws in 1984 relating to the export of material to form a patented combination invention off-shore. As part of the Patent Law Amendments Act of 1984, Congress responded to a 1972 Supreme Court case that had barred recovery for off-shore assembly of such a patented combination invention. Congress regarded its action as fixing a loophole in the patent law, *i.e.*, “respond[ed] to the United States Supreme Court decision in *Deepsouth Packing Co. v. Laitram Corp.* concerning the need for a legislative solution to close a loophole in patent law.” 130 Cong. Rec. 28,069 (1984).

Lilly would urge Congress to take a careful look at whether or not the current operation of the provision of the patent law in question, 35 U.S.C. §271(f), actually does plug a loophole in the patent law and whether – even if it did appear to do so in 1984 – that same analysis applies today. It appears that this provision in the patent law has not been widely used and, when applied to exportation of computer code, raises the potential for unintended consequences.

Lilly is not competent to speak for all the constituencies that might be affected by this change, but in the limited discussions of this subject of which we are aware, it appears to us that one viable option that Congress may wish to consider is outright repeal of this section of the patent statute, which might be preferable to a remedial provision engrafted onto a purported remedial provision that could run the risk of discriminating among patent rights based upon the field of technology.

Finish Off the Important Patent System Reforms Started in the AIPA

The American Inventors Protection Act started in motion important reforms to the U.S. patent law that have more than proven their merit. Like most legislation, the AIPA



contained a series of compromises that allowed new concepts put into U.S. patent law for the first time to be tested and validated. If Congress moves forward with first-inventor-to-file reforms, it will become very important for some of the first steps taken in the AIPA to move to their ultimate destination.

Lilly, therefore, urges Congress to move forward with AIPA-related reforms, including the following:

- Publish all pending patent applications at 18 months after initial filing. Adoption of the first-inventor-to-file principle removes the concern that publishing applications could spur patent filings by competitors that would ensnare the first inventor to file in patent interferences or could produce closely related patents by competitors who could “swear behind” the filing date of the published patent application. The first-inventor-to-file principle erases these concerns completely. It further offers the prospect for greater certainty in the patent system. Its adoption allows every inventor to have full knowledge of any prior filed competing applications that might impact the inventor’s ability to secure a patent.
- Remove the prohibition on seeking inter partes reexamination for patents sought before 1999 and relax the estoppel provisions such that issues not raised in the reexamination that could have been raised are not subject to any estoppel. With the adoption of a post-grant opposition system, a more effective inter partes reexamination law could represent a desirable complement.
- Permit filing of applications for patent by the assignee of the inventor, provided full identification of the inventor is provided. Assignee filing is permitted globally, except in the United States, and can often serve to protect rights that might otherwise be forfeited. Its use can simplify the formalities for filing patent application both domestically and internationally.
- Allow prior user rights for all types of inventions in commercial use (or for which substantial preparations have been completed for commercial use) that were reduced to practice by the prior user before the patent was initially sought. These simple changes to the prior user right statute represent an important complement to the adoption of the first-inventor-to-file principle. Moreover, these amendments could discourage off-shoring of manufacturing facilities to any of the many countries that already fully recognize such rights of a prior user.

Conclusions

Lilly has concluded that the time is ripe for a collection of major patent reforms. What remains difficult for us to assess is just how complete a package of such reforms might be achievable. Given the many voices and many ideas – indeed, many directions – for possible patent reforms, it is unclear whether the needed consensus will emerge to permit congressional action on some of the most important areas for reforms that have been proposed for consideration.

As we think through priorities for reform, the testimony of Director Dudas appears to us to require particular reflection. What can Congress do to make the everyday examining work of the patent office work proceed with greater efficiency?

Lilly would propose that Congress might begin by assessing what changes it could make to the patent statute that most directly impact the patent examining process. The first-inventor-to-file and accompanying “best practices” reforms represent an important step forward in this regard. Invention date proofs will no longer need to be laboriously considered by patent examiners; patent interferences (*i.e.*, the patent office proceedings used to decide who made an invention first) will largely disappear, and many conditions for patentability will no longer exist as potential issues for resolution during patent examination.

On the first-inventor-to-file issues, we may be blessed with a broad consensus for moving forward. The most important outstanding concern relates to the possibility for unintended limitations arising from the reformulated definition for prior art, *i.e.*, the effect on the right of third parties to obtain patents where an invention has been sold or otherwise used. It appears that these issues can be convincingly addressed.

Another “best practice” on which a consensus appears to exist relates to removing one of the “subjective elements” from patent litigation, the “best mode” requirement. This represents an issue that, when it arises in patent examination, is extremely difficult for the patent office to effectively address.

The next major area for reform that might provide the greatest benefit to the operation of the patent office lies in the APLA-sponsored changes to strengthen the effectiveness of the “duty of candor and good faith” by reining in “inequitable conduct” allegations. The idea of providing an incentive for patent applicants to procure entirely valid patents – by eliminating the “inequitable conduct” defense in such a circumstance – should allow Congress to institute a set of related reforms that could give the patent office control over the duty of candor and facilitate greater applicant responsibility in the patent examination process. This is an important priority for the patent office for the reasons expressed by Director Dudas.

Congress might consider then taking on the last of the “subjective elements” in patent litigation, the allegations of willful infringement. While many proposals for doing so exist, it appears that there is the possibility for a consensus to quickly emerge on meaningful reform that addresses many of the consequences arising from the current application of the “duty of due care.”

After these reform areas are addressed, the remaining areas for possible reform efforts become much more problematic. Enacting a fair and balanced post-grant opposition system rates very high on everyone’s list of things that – if done right – could remarkably improve the operation of the patent system and – if done wrong – could prove a colossal misadventure. Hopefully, on the many issues that separate the many interested



parties, common ground will emerge on a 9-month window for an effective system that can address all mistakes made by the patent office during the initial examination. Without an agreement on whether this is a short-window of opposition or a proceeding that could take place at any time during the life of a patent, it will be extremely difficult to get the fairness and balance right on the many other issues that need resolution.

All that said, we at Lilly still fear that too many discordant voices currently exist to be assured that a consensus can emerge on this issue.

Whether or not post-grant opposition can proceed based upon a consensus of views, we do believe that the AIPA-related issues can be accomplished, given that we see some significant consensus on what would be desirable and a strong rationale for action based upon adoption of the first-inventor-to-file principle.

Even if all the above reforms could be achieved, there are remaining important issues with the current operation of the patent system that Congress should not leave unaddressed and unresolved, provided that suitable reform proposals can be generated.

Most important among the remaining issues is the potential for abuse from the 100,000 continuing applications for patent filed each year. Congress needs to cajole interested parties to come forth with a viable proposal to address this issue that thus far has not been satisfactorily addressed.

On the last major policy issue, there is potentially more that Congress can do to assure that challenges to patents of doubtful merit are not unduly deterred. It may be that a viable proposal to respond to the issue of coerced settlements (*i.e.*, settlements induced because a business cannot take the litigation risk of an errant trial court decision) may emerge. To reflect that this is a complicated area is merely to perfect the understatement.

Without doubt, these are supremely important times for patent reform. The big questions appear to us to be how much and how fast. We would urge Congress to proceed as fast and as comprehensively as a consensus can be developed on proposals ripe for congressional action.



ROBERT A. ARMITAGE
 SENIOR VICE PRESIDENT AND GENERAL COUNSEL
 ELI LILLY AND COMPANY
 APRIL 25, 2005

Eli Lilly and Company believes significant reforms to the U.S. patent system should be a priority for Congress and is committed to working with all interested constituencies to assure that a broad consensus can be developed on the content of the needed reforms. In our view, the following may be ripe for congressional consideration:

- Adopt the first-inventor-to-file principle as part of U.S. patent law. Do so by maintaining the traditional inventor-focused features of U.S. patent law, including the inventor's 1-year "grace period" and so-called "self-collision" protections.
- Enact the consensus "best practices" for implementing a first-inventor-to-file system that include eliminating certain conditions for patentability that will be rendered unnecessary. Assure prior art is not diminished by clarifying that publicly accessible knowledge of an invention, whether through use, sale, offers for sale or otherwise, is all that is necessary to qualify as prior art.
- Increase the effectiveness of the "duty of candor" by creating an incentive for inventors to work with patent examiners to obtain wholly valid patents. Do so by barring any pleading of the "inequitable conduct" defense unless the court has found at least one patent claim is not valid.
- Repeal the "best mode" requirement, relying instead on the requirements for a complete written description and sufficient enabling details to permit the full scope of the claimed invention to be readily carried out.
- Limit the ability to plead that the infringement of a patent was willful except in cases that meet an appropriate standard for reprehensible conduct.
- If a fair and balanced structure can be defined and if accompanied by facilitating first-inventor-to-file and "inequitable conduct" reforms, open a 9-month window for post-grant opposition of an issued patent. Permit all mistakes in issuing a patent to be corrected in the proceeding.
- If pre-grant opposition prohibitions are maintained in force, provide a mechanism for consideration of third-party submissions of prior art and concise descriptions of the relevance of the submitted prior art.
- If an inventor's right to take reasonable steps to fully protect the invention can be maintained, eliminate the potential for abuse of the patent laws arising from the unlimited right to file continuing applications for patent.
- If a compelling policy basis is determined to exist, consider repeal (or other reform) to the so-called "off-shore" infringement provisions in the patent law.

At the same time, we urge Congress to reject calls for reforms that would:

- Prevent courts from stopping the continued infringement of valid patents.
- Limit any patent owner's damage award to an amount less than adequate to compensate for the infringement.
- Change the judicial burden of persuasion at trial for proving a patent is invalid.

**SMALL ENTITIES AND THE
“FIRST TO INVENT” PATENT SYSTEM:
AN EMPIRICAL ANALYSIS**

by

The Honorable Gerald J. Mossinghoff
Oblon, Spivak, McClelland, Maier & Neustadt

Foreword

by

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Senior Vice President and General Counsel

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ABOUT WLF'S LEGAL STUDIES DIVISION

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FOREWORD

by

Robert A. Armitage
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Gerry Mossinghoff served as President Reagan's Commissioner of Patents at the beginning of what many regard as the "modern era" of the patent system. President Reagan was committed – both domestically and as a cornerstone of U.S. foreign policy – to enhancing respect for patents as an inventor's *property right*. The U.S. patent system was transformed into an engine driving the growth of private investment in innovation. During Mr. Mossinghoff's tenure as the Reagan administration's chief IP policy advisor, Congress created a single appellate court to hear patent appeals – and charged that new court with bringing greater consistency to the law as it applied to patents. Congress then worked to address other shortcomings in the patent law and its administration. The successes of that era included strengthening of the financing of the United States Patent and Trademark Office and landmark reforms to the patent laws that simplified the ability of inventors to secure valid patents.

A quarter century has now passed since the beginning of the Reagan IP rights revolution. Congress is again taking a serious look at the need for reforms to the patent laws. It appears that both congressional subcommittees charged with oversight of the nation's patent system will be actively looking at a basket of reforms to the patent system – with United States Patent and Trademark Office financing again one issue likely to top the list of matters needing attention. Out-of-control patent litigation costs may be tackled through efforts to eliminate so-called "subjective elements" from most patent litigation (including the state-of-mind issues such as willful infringement allegations, inventor "inequitable conduct" charges, and best mode concealment contentions). Correction of mistakes made by the United States Patent and Trademark Office in the patent examination process may be addressed, possibly through adoption of some form of post-grant opposition proceeding. Finally, the core of the patent law appears destined for a close look. It appears likely that Congress will respond to longstanding calls for simplifying the set of requirements used to decide whether a patent application should be permitted to mature into a patent.

On the latter point, one of the most fundamental principles underpinning the patent system is garnering careful study: When rival inventors have independently made the same invention and sought separate patents for the same invention, which inventor – as between such rivals – should be permitted to patent that invention? U.S. patent law has traditionally favored the inventor that is able to prove a date of invention that was first in time relative his rival. This legal structure, however, forces a complex inquiry into the respective dates of invention of the rival inventors. The United States Patent and Trademark Office – and in some cases the courts – are required to sift through evidence of activities that took place years earlier. Despite safeguards, the process is not completely free from the potential for mischief and manipulation – or even fabrication. For many years, Congress barred the use of evidence of invention-making activities from outside the United States in order to avoid the possibility of deception that might go undetected.

The trade agreements that came into effect in the 1990s – NAFTA and the WTO – forced Congress to remove the bar on using foreign activities to establish an inventor's status as the first-in-time. Today, invention-making activities taking place in Shanghai have an equal footing under U.S. law as work done in Chicago. The same equality now exists between an inventor working in Delhi and one in Denver. Because of this requirement for global equality among inventors, U.S. patent law no longer operates to favor U.S.-based inventors at the expense of inventors working outside the United States. Indeed, because of the complexity and expense of the process, it now largely works in the opposite fashion. U.S.-based inventors, many of whom are so-called “small entities” (independent inventors, universities, other not-for-profit institutions, and small businesses) often have limited financial resources. When they become entangled in expensive and protracted “who did it first” contests, they frequently confront much better financed opponents, many of which are foreign corporations.

Following the treaty-mandated changes to U.S. patent law of the 1990s, a number of U.S.-based organizations have taken a fresh look at how the U.S. patent law operates to decide these contests among rival inventors seeking to patent the same discovery. The United States Patent and Trademark Office itself, as part of its efforts to better cooperate with foreign patent offices, has asked the U.S. private sector for help in understanding what might operate today as “best practices” for running the U.S. patent system – both for deciding how to resolve disputes among rival inventors and for setting the standards more generally for deciding whether a patent

should be issued for an invention.

The “best practices” discussions, which were initiated by the United States Patent and Trademark Office in 2001, have led to a remarkable consensus on the content of a 21st century U.S. patent system. That “best practices” consensus reaffirms much – perhaps most – of what is today part of U.S. patent law. The U.S. patent law should remain an inventor-focused patent law; the patent right should remain as a property right of the inventor, unless and until the inventor assigns that right to someone else. Unique and important features of U.S. patent law, such as our “grace period” that prevents an inventor’s own disclosures (made during the one-year “grace period” before a patent is sought) from being used to deny the inventor a patent, have been reconfirmed as “best practices.”

Another element of that “best practices” consensus supports eliminating our system of requiring proofs of dates of invention to decide which inventor among rival inventors should be permitted to patent the invention. In place of this principle, the first inventor to file for a patent would be permitted to patent the invention. The organizations supporting these dual conclusions that the United States should retain important inventor-focused features of U.S. patent law, yet make this fundamental change when dealing with rival inventors, includes bar associations, leading science institutions and major industry groups. Earlier this year, the American Bar Association resoundingly reversed a contrary position on first-inventor-to-file taken in the 1960’s. Last year, the National Research Council of the National Academies – after a five-year study of the patent system – made the first-inventor-to-file reform to U.S. patent law one of its seven principal policy recommendations. Finally, industry groups, including the Biotechnology Industry Organization, the Business Software Alliance, and the National Association of Manufacturers, have expressed a desire for harmonizing changes to U.S. patent law, the key to which is movement to the first-inventor-to-file principle.

One important question that must be addressed, however, is whether this fundamental change to U.S. patent law ought to be supported by the “small entity” constituency, especially the independent inventor community. Major reforms to the U.S. patent law, as they are subjected to the careful vetting that Congress will undertake, must take account of these constituencies. Will moving the entire patent system in the United States to “best practices,” including replacing the “date of invention” principle with a first-inventor-to-file principle truly benefit these inventors?

The intuitive answer to this crucial question should be an affirmative “yes.” The reasons are fairly straightforward. All the deficiencies of a system tied to proofs of dates of invention should be least impactful on the most resourceful, *i.e.*, “large entity” inventor community that includes multinational corporations. These deficiencies should, in theory at least, disproportionately impact on the “small entity” community – especially now that foreign-based inventors can compete for patents using evidence of work done outside the United States.

The features of the current law that should in practice impose particular hardships on the least resourceful, least well-financed inventors include the time it takes to make a final determination of which among rival inventors was first to invent. This exercise is typically prolonged – sometimes longer than the technological lifespan of the innovation. It is also enormously expensive. Sorting through an inventor’s records for potentially relevant evidence requires experienced patent counsel. It is also incredibly complicated. The United States Patent and Trademark Office proceedings used to determine who invented what first are noted for their arcane, even Byzantine character. At the end of the day the resolution of the “who invented first” question can cost an inventor hundreds of thousands of dollars (alas, spending *millions* of dollars on this determination is not unknown).

Mr. Mossinghoff’s WORKING PAPER makes a seminally important contribution to the debate over whether our existing patent law grounded on marshaling evidence of invention dates disserves “small entities” relative to a system grounded on the first-inventor-to-file principle. The debates during the 1990s were often inconclusive on the key issue of whether “small entities” were victimized by – rather than beneficiaries of – the *status quo*.

Gerry Mossinghoff’s work now responds to these issues with facts – an exhaustive look over decades at what actually happened in the United States Patent and Trademark Office when rival inventors set out to prove who invented first. Those facts make clear that using the first-inventor-to-file principle as a core principle of reformed U.S. patent law would best protect the interests of the independent inventor. Indeed, over the past several decades, Mr. Mossinghoff’s analysis reveals that our current patent law has cost the independent inventor community more patents than it has secured for them. Moreover, in the years since foreign-based evidence has been able to be used to decide these issues, the rate of loss of patents by independent inventors appears to be accelerating.

Finally, with this cornerstone change to U.S. patent law in place, it becomes vastly easier for Congress to build other improvements in the patent law around it. Other “best practices” changes would simplify the patent examination process itself. Post-grant oppositions could be more effective and efficiently operated in order to correct mistakes made in granting patents. Patent litigation costs could moderate with a patent law focused on fewer, simpler and more objective issues relating to whether an invention had been validly patented.

The process of building a consensus on the various elements of a broadly based patent reform will likely continue through the 109th Congress. The strong foundation for that building process can be traced back to the pro-property rights policies that Gerry Mossinghoff helped cement into place in the early 1980’s. Upon that foundation, this paper provides walls of hard data that should make sturdy building materials.

**SMALL ENTITIES AND THE
“FIRST TO INVENT” PATENT SYSTEM:
AN EMPIRICAL ANALYSIS**

By

The Honorable Gerald J. Mossinghoff
Oblon, Spivak, McClelland, Maier & Neustadt

INTRODUCTION

As between two true inventors claiming the same invention — as contrasted with copiers — *every* nation in the world, except the United States, grants the patent to the inventor who first undertakes to use the patent system to disclose his/her invention to the public and gain protection.¹ In shorthand, this is called a first-to-file system of priority, but it is more appropriately called a first-inventor-to-file system. For reasons that perhaps made sense historically, the United States has a so-called first-to-invent system of priority that is intended to grant a patent to the first “inventor,” i.e., the first person to “conceive” and/or “reduce the invention to practice” under an arcane and burdensome complex of substantive and procedural rules and regulations governing what are called “interferences”

¹At the end of 1997, there were two nations that used the so-called first-to-invent system: the United States and the Philippines. Effective January 1, 1998, under its Republic Act No. 8293, the Philippines adopted a first-to-file system, leaving the United States alone in the world in adhering to the first-to-invent system.

in the U.S. Patent and Trademark Office (“USPTO”).²

As early as 1965, a major Presidential Commission studying the United States patent system strongly recommended that the United States adopt the otherwise universal first-to-file system.³ Given the increasing use of low-cost and easily filed *provisional applications*, such a system would be of significant benefit to small entities — the class that comprises independent inventors, small businesses and nonprofit institutions.

²In an article published at 82 JPTOS 891 (December 2000), Charles L. Gholz, an internationally recognized expert on interference practice, described graphically what can happen in an interference:

A couple of years ago I was handling a big ticket interference in which my side's inventors were named the Inventors of the Year by the Intellectual Property Owners Association. At about the same time, my client assigned the lead inventor to us full time. That is, it told him that it was more important for him to work with us to win the interference than it was for him to work at his laboratory bench making more inventions!

My client's decision was good for us, but it was grotesquely bad for the nation. While the inventor spent his time racking his brain trying to remember what he had done and when he had done it years before (and more importantly, trying to find documents to substantiate his hazy memory), he could have been back at his bench making more important inventions.

As things stand, important people (i.e., inventors—not patent attorneys!) spend enormous amounts of time on historical matters which, at least in most cases, are of absolutely no use to anyone apart from the interference and of no interest to anyone at all for any reason. 82 JPTOS at 894.

³“To Promote the Progress of ... Useful Arts” in an Age of Exploding Technology, Report of the President's Commission on the Patent System, Washington, D.C. (1966). This is not a partisan matter. The 1966 Commission Report was to President Johnson. In August 1992, the Advisory Commission on Patent Law Reform reached virtually identical conclusions in its report to the Secretary of Commerce in the Bush Administration. The Advisory Commission on Patent Law Reform, Report to the Secretary of Commerce (Aug. 1992). For a discussion of the advantages of a first-inventor-to-file system, see William S. Thompson, *Reforming the Patent System for the 21st Century*, 21 AM. INTELL. PROP. L. ASS'N. Q.J. 171 (1993).

However, assertions are heard that adopting a first-inventor-to-file system in the U.S. would somehow favor large companies to the disadvantage of small entities.

I. ESTABLISHMENT OF THE SMALL ENTITY STATUS

To provide adequate funding for the USPTO, I recommended in 1981 to the Secretary of Commerce and he in turn recommended to the President through the Office of Management and Budget (1) that the user fees for patents and trademarks be substantially increased and (2) that the USPTO be able to use the increased fees to fund its operations instead of those fees being deposited in the miscellaneous receipts of the U.S. Treasury. That recommendation was sent to the Congress in connection with the Administration's FY 1983 Budget, and Congress enacted it in P.L. 97-247.

A key part of the statutory patent fee structure enacted at that time was that it established a two-tier fee system that we had recommended. That two-tier fee system allows qualifying independent inventors, small businesses and nonprofit institutions — referred to collectively as "small entities" — to pay half of the standard patent filing fees, patent issue fees and patent maintenance fees.⁴

Thus, since fiscal year 1983, the USPTO has been able to keep track statistically of all patent applications that it receives and of all patents that it

⁴35 U.S.C. § 41, 37 C.F.R. §§ 1.16 et seq.

grants by four categories: (1) independent inventors, (2) small businesses, (3) nonprofit institutions and (4) large entities. Using the data thus collected by the USPTO — from the initiation of the small entity status in 1983 through fiscal year 2004 — this WORKING PAPER will document what happened historically to small entities when they became involved in interferences, i.e., the USPTO procedure used when two parties claim the same invention at nearly the same time.

II. DEFINITION OF TERMS

This paper will say that:

- ♦ a small entity was *advantaged* by the first-to-invent system if the small entity was the *junior party* in an interference — i.e., the second person to file a patent application on the invention — and received a *favorable* decision.
- ♦ a small entity was *disadvantaged* by the first-to-invent system if the small entity was the *senior party* in an interference — i.e., the first person to file a patent application on the invention — and received an *adverse* decision.

III. STATISTICAL HISTORY, 1983 –2004

From 1983 through 2004, the USPTO received 4,500,649 utility, plant and reissue applications and granted 2,456,479 such patents. During that same period there were a total of 3,253 two-party decisions in interference cases, a tiny fraction of the applications filed and patents granted. Using the number of applications filed as the denominator, the

number of two-party decisions amounted to less than one in 1000 (0.1%) of the applications filed. Using the number of patents granted during the 22-year period as the denominator, the percentage of two-party decisions increases but is still less than two in 1000 (0.2%) of the patents granted.

Based upon an analysis of the small entity data that now exists, the USPTO reports that the number of small entities that were *advantaged* by the first-to-invent system during the 22 years — 1983–2004 — was 286, whereas the number of small entities *disadvantaged* was slightly higher, namely, 289. (Figure 2).

- ♦ 50 non-profit institutions were advantaged and 30 disadvantaged. (Figure 3)
- ♦ 97 Small Businesses were advantaged and 92 disadvantaged. (Figure 4)
- ♦ 139 independent inventors were advantaged and 167 were disadvantaged. (Figure 5)

Figure 6 shows these data on the same scale.

Those of us who believe that adopting the first-inventor-to-file system of priority in the United States would actually favor small entities point out that the current system of forcing a small entity into an interference proceeding with a large and determined company that filed a patent application *after* the small entity could cost the small entity hundreds of thousands of dollars, even if it ultimately received a favorable decision. More importantly, small entities by their very nature can move more quickly

than larger bureaucracies. And here is where the United States *provisional application* comes into play. By filing a complete technical disclosure of the invention, a small entity can readily secure priority rights in a first-inventor-to-file system without a major expenditure of resources. This then gives the small entity a year in which to file a professionally prepared patent application.

The data provided by the USPTO confirm empirically that the current first-to-invent system of priority provides no advantage to small entities. Figure 6 speaks for itself. Historically, virtually the same number of small entities were advantaged by the first-to-invent system (286) as were disadvantaged (289). And with respect to independent inventors — among the most vocal of first-to-invent adherents — more were disadvantaged (167) than were advantaged (139) by the first-to-invent system.

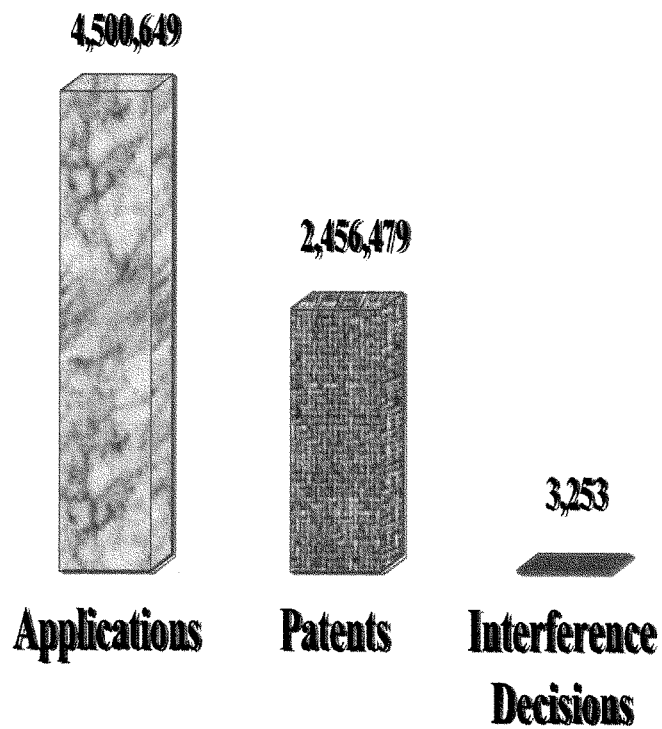
CONCLUSION

There are many good reasons why the United States should join the rest of the world in adopting a first-inventor-to-file system — reasons well beyond the scope of this brief paper. Hopefully, the data presented in this paper — based on 22 years of actual experience — will add constructively to the debate on this very important public policy issue.

Figure 1

U. S. PATENTS, APPLICATIONS & INTERFERENCE DECISIONS

1983 - 2004



A-1

Figure 2

SMALL ENTITIES

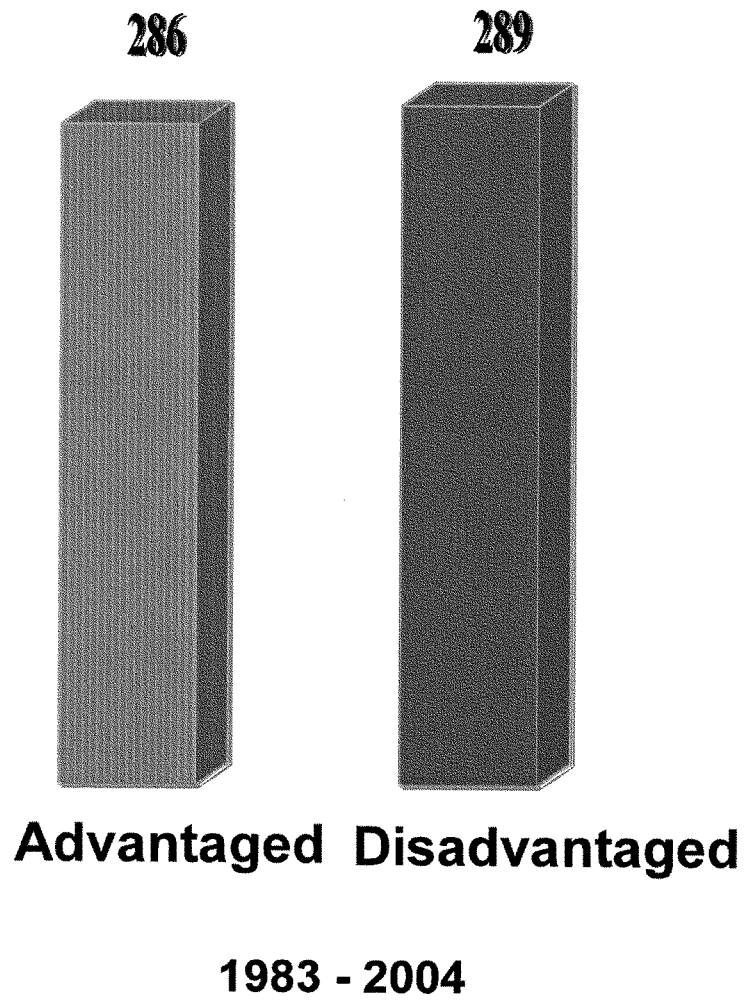


Figure 3

NON-PROFIT INSTITUTIONS

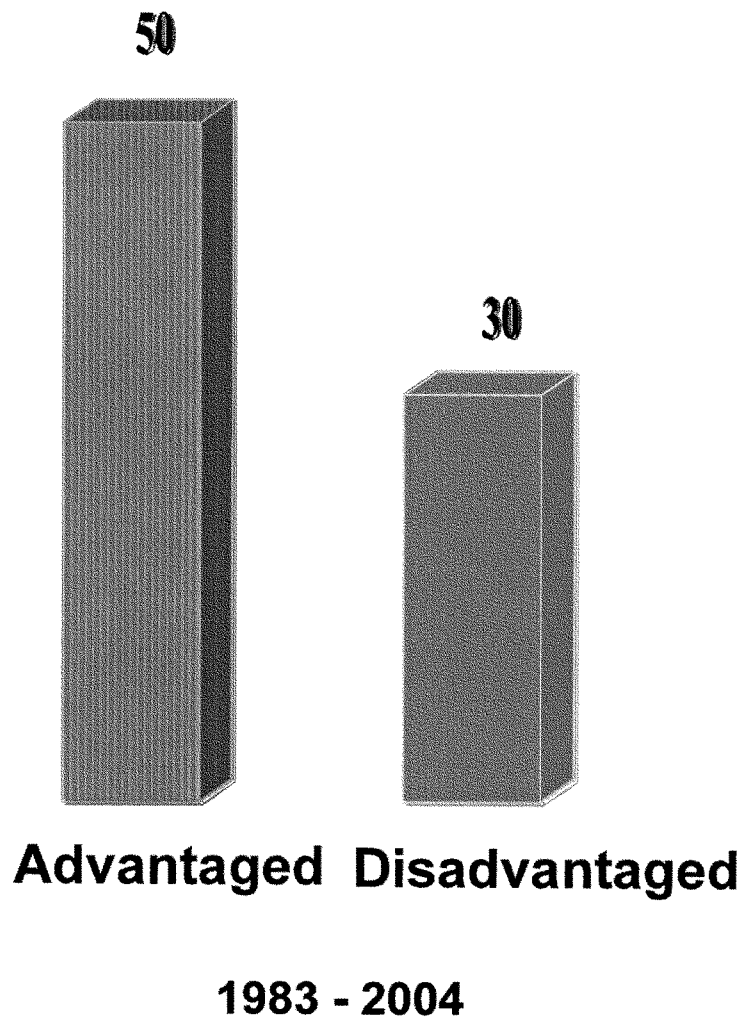


Figure 4

SMALL BUSINESSES

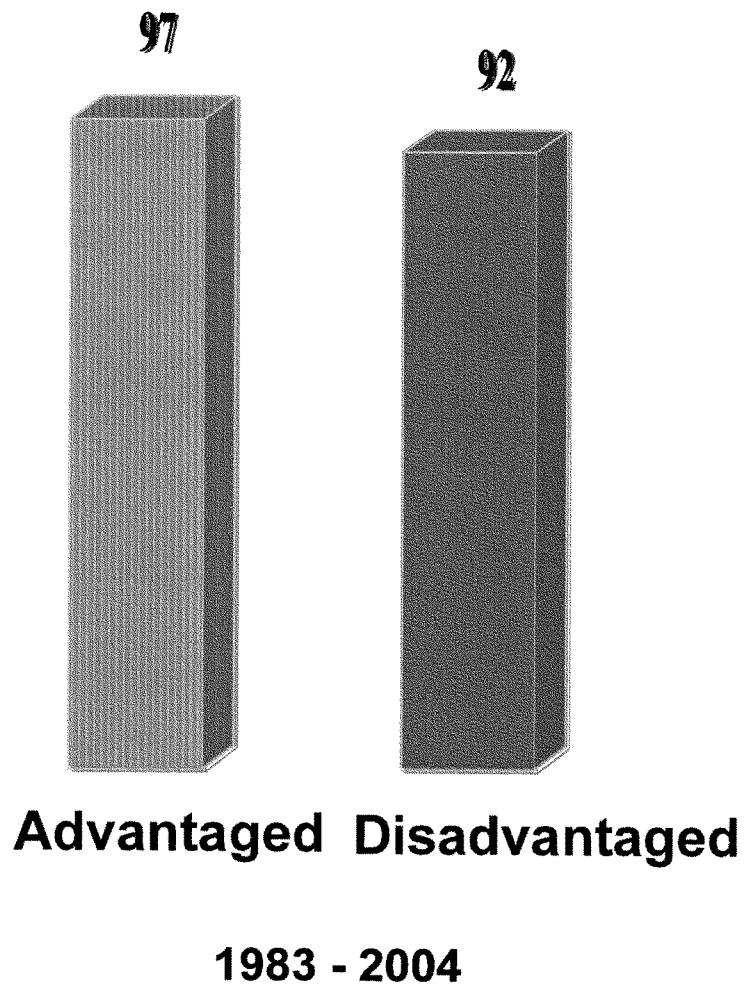


Figure 5

INDEPENDENT INVENTORS

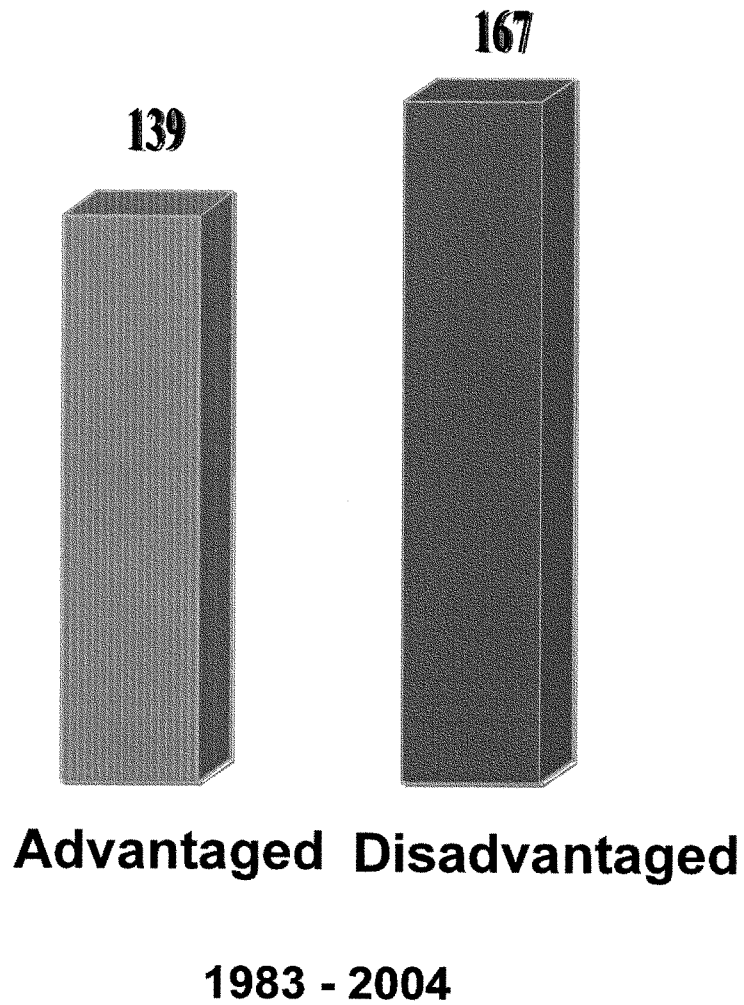
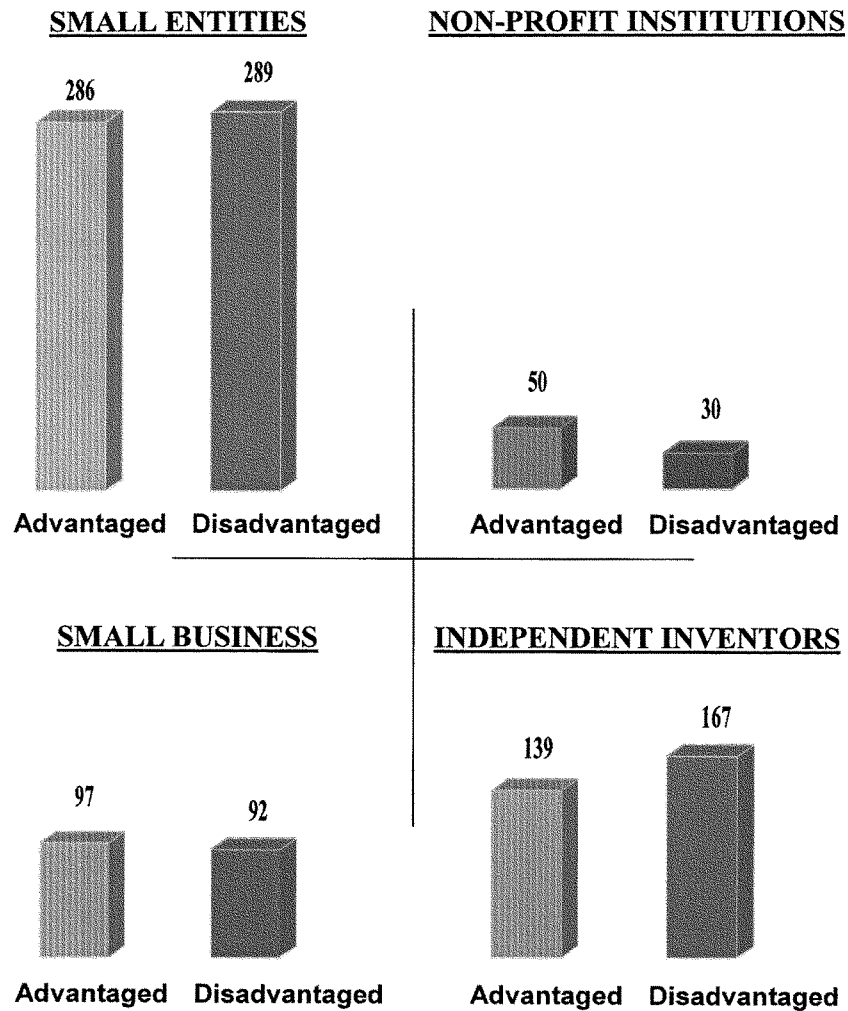


Figure 6**1983 - 2004**

STATEMENT OF

THE HONORABLE JON W. DUDAS

**UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE**

BEFORE THE

**SUBCOMMITTEE ON INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
United States Senate**

“The Patent System: Today and Tomorrow”

APRIL 21, 2005

Introduction

Chairman Hatch, Ranking Member Leahy, and Members of the Subcommittee:

Thank you very much for inviting me to testify today. I commend you for holding this hearing appropriately named the “Patent System: Today and Tomorrow.” This is a particularly appropriate time to reflect upon the incredible success of innovation and of our patent system in the United States. It was 215 years ago this month that our young nation adopted its first patent statute. On April 5, 1790, your predecessors in the Senate passed the final version of the statute, and President George Washington signed it into law on April 10.

The benefits of our patent system have always been obvious to Americans. You are familiar with Article 1, Section 8, Clause 8 of the U.S. Constitution, granting Congress the power “to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” James Madison wrote in one of the Federalist Papers, “The utility of this power will scarcely be questioned.” He was right. That clause was adopted into the Constitution without a dissenting vote -- without even any recorded debate.

The need for a statutory system to examine and grant patents was just as obvious. President Washington signed the first patent statute 215 years ago -- before our nation even had its 13th state. History has repeatedly affirmed the wisdom of this decision of our Nation’s founders. The tremendous ingenuity of American inventors, coupled with

an intellectual property system that encourages and rewards innovation, has propelled our nation from a small agrarian society to the world's preeminent technological and economic superpower.

The flexibility and strength of our patent system have helped entire industries flourish, rather than perish. Everyone has benefited from the innovative products encouraged by this system. And all of the technology encouraged by the patent system finds its way to the public domain within 20 years -- freely available to any and all.

The success of the patent system is not limited to the United States. It is the basis for economic development in nations throughout the world. Unfortunately, a growing chorus of critics is asking if the fundamental patent system that has been so critical to the growth of innovation and economic success in the United States and other nations will enhance or hinder development in their nations.

Today, many of the nations questioning the efficacy of an intellectual property system have become hotbeds for the manufacture and export of counterfeit goods. Unsurprisingly, some of the nations that allow their citizens to counterfeit and pirate others' intellectual property are the very ones questioning a system that encourages and rewards innovation, and discourages copying and free riding.

The USPTO Today and Prominent Issues

In the last several years, intellectual property (IP) assets have become an ever more essential ingredient of economic vitality. In the past, raw materials and other tangible goods were the main drivers of an economy. Today, economic success depends increasingly on intangible, information-based assets, such as the creativity of employees and the knowledge gained from research. As a result, intellectual property-based industries, such as biotechnology and entertainment, now represent the largest single sector of the U.S. economy. In fact, IP industries export more American value to the world than the automobile, automobile parts, agricultural, and aircraft industries combined.

As the clearinghouse for U.S. intellectual property rights, the USPTO is an important catalyst for U.S. economic growth. Through the grant of patents and the registration of trademarks, the USPTO promotes the economic vitality of businesses and entrepreneurs, paving the way for investment capital, research and scientific development.

We are proud of our 200 year-old legacy of partnership with America, providing the tools for our nation to become a technological and economic giant. **To continue this partnership, we must remain the best patent-examination system in the world. To ensure on-going success, the USPTO must focus on improved quality and productivity. To ensure timely grant of rights, we must reduce our backlog of patent applications by increasing our efficiency and taking advantage of our automation efforts.**

Intellectual Property: Increasing Importance and Complexity

Globally, intellectual property protection is more relevant than ever. Worldwide, 12 million patent applications are pending –in the European Patent Office, the Japan Patent Office, and various national patent offices. Without question, the growing importance of intellectual property protection has a direct impact on the USPTO. Patent applications in the United States have more than doubled since 1992. In the last five years alone, biotechnology-related patent filings at the USPTO increased 46 percent, while pharmaceutical and chemical-related filings climbed 42 percent. As a result, the USPTO issued more patents *last year alone (173,000) than it did during the first 40 years of its existence.*

While the sheer volume of applications is staggering, the technical complexity of patent applications is escalating rapidly. In 1905, more than one-third of U.S. patent filings were bicycle-related. Today, the USPTO routinely examines patent applications in areas such as nanotechnology, bio-informatics, and combinatorial chemistry - - art areas that didn't even exist one hundred years ago. Some patent applications are received on CD-ROMs, containing literally the equivalent of millions of pages of data on paper.

The Patent Applications Backlog

The dual trends of increased volume and complexity of patent applications filed pose significant challenges for the USPTO. While the volume and technical complexity of patent applications have increased significantly, our capacity to examine patent applications has not risen at the same rate. The result is a pending-application backlog of historic proportions. In essence, we face a unique historical challenge: how to handle record levels of complex work in an efficient manner, without the benefit of a precise role model.

Patent pendency (the amount of time a patent application is pending before a patent is issued) now averages more than two years. In more complex art areas such as data-processing technologies, average pendency stands at more than three years. Without fundamental changes in the way USPTO operates, average pendency in these areas could double by 2008. Moreover, without intervention, the backlog of applications awaiting a first review by an examiner could grow from its current level of approximately 500,000, to over 1,000,000 by 2010.

To put these pendency numbers in perspective, in 1981 when the U.S. patent system was faced with a workload crunch, *U.S. News & World Report* published an article on the situation entitled "Patent System a Drag on Innovation." At that time, average patent pendency was 22 months and the backlog of unexamined cases was 190,000. Today, as the numbers above show, the pendency predicament is far more dramatic. The problem arises because both the nature of technology and the nature of the marketplace make long processing delays unacceptable -- and unsustainable.

If intellectual property protection is to continue to serve its purpose as a catalyst for technological innovation and economic growth, the USPTO must fundamentally break with the status quo. If we are to issue quality patents and register quality trademarks in a

timely manner, we must fundamentally reform the way we do business. Fortunately, Mr. Chairman, thanks to the leadership you and many of your colleagues in the House have shown, the USPTO has been appropriated the funds we need to face these challenges. We know, however, that simply using appropriated resources will not alone do the job. We must be prudent in developing the processes that will make the patent system more effectively serve its purposes.

Summary of Critical Issues

Due to the record growth that began in the 1990s and continues today, the USPTO is facing a record workload crisis. The rate of growth of patent applications has slowed, but we continue to receive record numbers of applications every year. Unless the bold new actions described below are taken, progress on our quality enhancement and electronic government initiatives will be in jeopardy, the backlog of unexamined patent applications will skyrocket, and average patent pendency will dramatically increase.

USPTO: Working to Improve our Patent System

Given our workload challenges, we are considering a variety of internal reforms that will continue to enhance patent quality and address our increasing pendency challenges. It is our responsibility not only to do everything we can to perfect the patent system in the United States -- something you too are doing by holding this hearing. We must actively educate the world that it is fundamentally the best patent system.

The right fundamentals alone though are not enough. I am the first to acknowledge that even the best system in the world can and must improve. Today, we are implementing a range of improvements and are building on existing initiatives. We are also working on a series of potential legislative improvements to the system. The future requires that we work both domestically and with our international counterparts to develop the best patent system -- in terms of patent quality and performance - for inventors both here at home and abroad.

We applaud the Committee for examining our patent system with an eye to improvements that it can make. We are also looking internally at the improvements that the USPTO can make through the authority that Congress has given it.

Making commitments and keeping them has led to some successes throughout the USPTO organization, including the implementation of the President's Management Agenda and the *21st Century Strategic Plan*. The USPTO is now better equipped to handle the many important challenges that face our nation and our IP system at home and abroad.

Earlier this year, the USPTO announced additional initiatives that will improve quality and efficiency—**increasing transparency, internally improving *ex parte* reexamination, and saving applicants tens of millions of dollars by revamping our process concerning the submission of appeal briefs by applicants during the**

examination process. We continue to make commitments, and we will continue to keep them.

Improving Transparency and Enhancing Quality

As a measure to enhance quality and public confidence in our office, I have committed the USPTO to provide improved transparency in our operations. The USPTO will continue to report to the public more information, better information, and more meaningful information about our office and its performance. You will see us measure ourselves more often, more intensely, and with more useful data -- data that will not only report quality and pendency statistics at the USPTO, but will present a basis for improvement.

While implementing electronic tools to assist employees of the USPTO in doing their jobs, the USPTO has also provided Public PAIR -- the Patent Application Information Retrieval system -- to assist and benefit the public. Public PAIR allows anyone access to the entire file history of an application, including access to images of every paper of record for every published application in our database. With the click of a mouse, Public PAIR provides innovators information that is critical to understanding how a technology is evolving. This will help American industry better target its research and development investments, and be more responsive to the demands of the national and global marketplaces. Its counterpart for unpublished applications -- Private PAIR -- lets applicants access the entire file history of their applications in our Image File Wrapper ("IFW") database, saving time for both applicants and examiners. These systems are truly milestones of achievement for the agency.

In the past, our pre-grant sampling of allowed patent applications showed an error rate that fluctuated between 3 percent and 7 percent. Our metrics were not as effective as they could have been in helping us evaluate and train our examiners about what went wrong and how to avoid that type of error in the future. Starting with the *21st Century Strategic Plan*, we re-assessed ourselves. Today, we conduct more general reviews and more in-process reviews. We now have meaningful data from which to calculate quality baselines. We use that information to identify points of error, and thereby to adjust training and interactions with examiners to improve our processes and our examination.

We now review more work, and we review it in a smarter way. In some areas, we have tripled our number of reviews. We are looking at our error rates more deeply, and dissecting the issues causing errors. We can and are developing specialized training for examiners based on results from in-process reviews of our examiner's work. And, as an enhanced quality measure, we have expanded a "second-pair-of-eyes" review in certain technology areas.

Finally, until recently, our pendency measures were not meaningful enough from the perspective of managing an office. Old ways of measuring pendency did not illuminate all issues and could be misleading. As noted above, precise information regarding both pendency and our backlog is critical to informed management decisions. I have directed that our pendency statistics be supplemented by additional measures that more fully

reflect the current state of affairs in the USPTO, with the goal of identifying specific ways in which we can improve.

Our users will now know more of what we know. Provided with better information, our customers can have enhanced insight to the patent-examination process and will be encouraged to offer constructive recommendations for systemic improvement.

Improving the Reexamination Process

Many of the quality issues raised and debated today in the patent system are within our reexamination system. Without entering the debate on the limitations of *inter partes* reexamination, legislative improvements, or even post-grant review, there is no question that the USPTO can do much to improve the reexamination process.

By way of background, we are focused on improving the reexamination process because it is an opportunity for the public to assess patentability without resorting to costly litigation. An *ex parte* reexamination proceeding is conducted within the USPTO when any person, including the patentee, submits a substantial new question as to the patentability of the subject matter of an issued patent. The statute authorizing reexamination proceedings requires the USPTO to conduct this process with "special dispatch." Frequently, these proceedings require more than 100 hours of examiner time to complete. And today, a large number of reexamination proceedings have been pending before the USPTO for more than four years without resolution. We are just as dissatisfied with these results as are the stakeholders in the system.

As I mentioned earlier, reexamination proceedings are important to patent owners and to the public as a means of resolving the issue of patentability without resorting to the high-cost option of litigation. In these proceedings, both timeliness and correctness of the decision are important to all parties to provide certainty of intellectual property rights. Therefore, we have an especially important duty to get it right here with special dispatch. However, many reexams are complex and time-consuming. Sometimes there is intentional delay on the part of those outside the USPTO, which can add to the time it takes us to process reexams.

Proposed Reexamination Improvements

To address issues of timeliness and correctness of the decision, the USPTO will implement a new process for handling reexamination proceedings. Our goal is that, by the end of FY 2005, we will have resolved all instances of *ex parte* reexamination proceedings that have been pending with an examiner for more than two years. Specifically, of the current 1,200 pending *ex parte* reexamination proceedings, we hope to resolve 420, or over one-third of our current reexamination workload. If we had not undertaken this challenge, the total number of reexaminations pending for more than two years would have risen to 600 by the end of this year. An additional commitment is that, by the end of FY 2005, the USPTO will set a defined time period for all future *ex parte* reexamination proceedings to be completed before the examiner, and the period will be less than the two years achieved in fiscal year 2005.

A similar clean-up effort is being conducted for all *inter partes* reexamination proceedings now pending before the USPTO. To address the issue of the correctness of the decision, the USPTO will require supervisory review of all USPTO decisions in any reexamination proceeding. It is expected that this process will employ a panel of least three supervisors and senior patent examiners. Further, by the end of this fiscal year, the USPTO will establish firm processing time periods for all reexamination proceedings ordered (after the Office order for reexamination) on or after October 1, 2005, for both *ex parte* and *inter partes* reexamination proceedings.

Making Pre-Brief Appeal Conferences More Citizen-Centered

Pre-Brief Appeal Conferences are another area where we are implementing the President's Management Agenda mandate that government be citizen-centered (not bureaucracy-centered) and results-oriented, by eliminating certain patent processing costs for citizens.

Today, when an applicant wants to appeal a patent rejection with the Board of Patent Appeals and Interferences (BPAI), the applicant must file a Notice of Appeal and an Appeal Brief outlining why the examiner's position is in error. The next step is an Appeal Conference with the examiner who decided the claims were not patentable, joined by the examiner's supervisor and another experienced examiner or supervisor. Only after this conference does the examiner prepare an Examiner's Answer explaining why the application is not allowable.

Currently, after the Appeal Conference, approximately 60 percent of cases are not forwarded to the BPAI for a decision. A conservative estimate of costs to applicants for preparing and filing the 60 percent of the Appeal Briefs that are never forwarded to the BPAI is \$30,000,000. To save applicants at least \$30,000,000 annually, the USPTO will implement a program in the third quarter of FY 2005 that allows applicants to request an Appeal Conference before preparing an Appeal Brief.

For a Pre-Appeal Brief Conference, it is not necessary for the members of the Appeal Conference to review the full Appeal Brief to determine whether the examiner's action on that particular application was proper and should proceed to appeal. If the Appeal Conference determines that the examiner's decision was not proper, the applicant will be notified that an appeal to the BPAI is not necessary at this time, thereby saving the applicant the cost of preparing and filing an Appeal Brief. If the Appeal Conference determines that examiner's decision was proper, the applicant will be notified to file an Appeal Brief in order for the application to go forward to the BPAI for a judicial decision. To assist in this evaluation, the USPTO has this month (April 2005) initiated a new pilot program to create a corps of appeal conference specialists, who will be trained in the way that the BPAI judges would review an appeal once it reached the Board.

Post-Grant Review

As part of our 21st Century Strategic Plan, we proposed a legislative initiative – Post-Grant Review – to address patent quality, as well as the badly needed patent litigation reform that is being advocated in many quarters. Post-Grant Review has great support

among all major patent interest groups, including the bar, technology companies, academicians, and others seeking patent reform. Simply put, “post-grant review” will give the public another vehicle for reviewing the quality of issued patents. We believe our proposal promotes innovation by ensuring that the patent system is fair to all. By “fairness,” we mean it promotes a patent system where flaws in issued patents can be quickly and expertly revealed, without exposing a patent holder to frivolous or even mischievous review and uncertainty. We look forward to working with the Committee in helping it design the most effective and fair post-grant review process.

Other Reform Initiatives

We have increasingly recognized that, when the USPTO receives 375,000 patent applications a year, the task of maintaining and improving a sound patent system must be shared by patent applicants and their representatives, as well as by the USPTO. One aspect of the Strategic Plan addressed the concept of shared responsibility through a proposal for mandatory continuing legal education for registered patent practitioners with respect to laws affecting practice before the USPTO. We are currently developing the means for making such education equally available to all practitioners via the Internet and through Continuing Legal Education (CLE) providers.

As an agency, we are focusing our operational improvement initiatives on our examiners and other employees who are keys to the success of the patent system. We are using a better training process, and are updating our employees’ skills throughout their careers.

I do not purport to have all the answers to address all the challenges faced by the patent system. However, I can assure you that we are reviewing the USPTO’s role as part of the system, and we will welcome the opportunity to share what we learn with you and how we believe we can appropriately address the issue of application quality.

I certainly will not shy away from focusing on how we can improve processes at the USPTO. As you know, we have spent the last three years doing just that, and I am thankful that you passed legislation that will give us many of the tools we need to make the necessary improvements. I fully appreciate that you will hold the USPTO agency accountable for addressing shortcomings and am confident that we will deliver results on issues of concern.

Over Two Full Centuries of Partnership With Customers

Our system continues to prove its strength through the new inventions described in patent applications we see every day, the growth of investment, and the fact that the Office receives record numbers of applications each year (i.e., 375,000 new patent applications last year alone). We encourage new applications. Unfortunately, many of the applications we are examining are not new. In fact, an important exacerbating factor with respect to the tremendous volume of the workload is the amount of rework cases we see in the form of “continuation” applications. While there may have been a time where the system could afford duplication and redundancy, that time has passed.

We have an incredibly dedicated core of patent examiners and technical support staff. I have met with hundreds of examiners individually, collectively, in tech center meetings, at union meetings, at retirement parties, and just walking the halls. Those who stay and make a career at the USPTO are dedicated, engaged, and knowledgeable. They not only know their art, but also are keenly aware of the outside pressures on our office. Interestingly, the number-one challenge I hear from examiners is that of problems with incoming application quality! The comments from our examiners emphasize to me, possibly more than anything else, how much of a shared responsibility patent quality is and improvement to the patent system.

The Impact of “Continuations” on the USPTO

Last year, more than 100,000 of the 355,000 applications filed with the USPTO were iterations of applications that had previously been reviewed by an examiner. That is, more than one-third of the applications received last year were not, strictly speaking, “new.” Rather, they represented a form of re-work. This rework is a significant challenge for reaching new applications, because so-called continuations represent additional work on subject matter that has already been reviewed in examination and – in some instances – even issued as a patent. Continuations, or “re-work,” can take a variety of forms. A “continuation,” per se, is a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented. A “divisional application” is a later-filed application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application. An “RCE” (request for continued examination) is available in an application where prosecution is closed, at the request of the applicant. Given the ever-increasing workloads we face, it is necessary and appropriate for all to consider whether some restrictions should be placed upon so-called “continuation” practices.

Patent Applications and the Number of Claims

Patent applicants include, as part of their application, patent claims that ultimately define the legal metes and bounds of the protection when a patent is granted. Thanks to your efforts last year, the USPTO now receives additional funding to support our examination function through fees based upon the number of claims presented for examination. Tying increased fees to increased numbers of claims inserts the right monetary incentives in the system. What is not immediately evident is that even a relatively small number of applications containing a large number of claims present efficiency challenges. Complexity of analysis is directly related to the number of claims presented, and large numbers of claims immediately affect our examiners’ ability to conduct the high-quality examination we all expect from our patent system. It is not solely a question of time. Large numbers of claims may involve numerous interactions with possibilities not envisioned by even the applicant. Accordingly, the burden imposed by such large-claim applications – even when received in relatively small numbers -- can impede our ability promptly to examine applications relating to other inventions. At the same time, we must certainly recognize the legitimate need for applicants to present large numbers of claims in some applications.

What we must do is find the right balance. We must find ways in which inventors can submit large numbers of claims when needed, while making it feasible for examiners to effectively analyze a plethora of claims. Currently, about 7 percent of applications present about 25 percent of the patent claims we examine. That is, a minority of applicants (7%) creates more than 25% of the claims-review work. We are considering the possibility of requiring applicants who file these so-called “super-sized” applications to help us by identifying the relevant issues.

Increased Applicant Responsibility

We are also considering additional rules changes that would require those applicants who place relatively greater stresses on the system to assist the USPTO with efficient processing of applications. For example, applications filed with large numbers of claims represent challenges to timely processing, particularly for examination. Applications filed with large numbers of prior art references, without any guidance as to which references the applicants believes to be most relevant, have an impact on efficient examination. We believe that the patent system as a whole is better served where applicants work in partnership with the USPTO to take responsibility for efficient processing of applications. We want a patent examination system that “gets it right” the first time. Concentrating our review on the most pertinent information relevant to patentability is an efficient means to “get it right” the first time. For applicants, quick, accurate focus on relevant prior art means their applications are properly assessed, and amendments or changes to the patent application and claims can be suggested with confidence. Ensuring such a focused examination is a joint responsibility of the examiner and the applicant. By working to improve the ways that the best, most relevant information comes before the examiner, we will best achieve the goal we all share of high-quality patent grants that have the respect and trust of the entire patent community, both domestically and internationally.

The USPTO and Tomorrow

The USPTO is a team of 7,000 people, including scientists, engineers, and PhDs, many of whom spend their time considering how we might improve our patent system. A multitude of others outside of the USPTO also are reflecting upon our system, and are likely to approach you with suggested changes.

While we have much to be proud about in our system, there is much talk about whether our patent system should be reformed. Two recent reports by the Federal Trade Commission and the National Academies of Sciences call for a variety of patent system reforms. While such studies have earned enormous attention from the media, it is important to underscore that much of what they discuss is not new. In fact, several of the proposals suggested reflect ideas that were first developed and discussed by the USPTO.

At the USPTO, we have had experts working on patent-reform issues for decades. We welcome the discussion of many of these initiatives as part of a legislative package that you may introduce later this year. We presently are hearing of legislative proposals in

three general categories: operational issues; litigation reform; and convergence of international laws and best practices. In my view, each of these discussions must center on how the patent system encourages innovation, and how well it serves the public at large.

In my capacity as the Under Secretary of Commerce for Intellectual Property and the Director of the Office that must examine these applications, I am pleased to work with you on patent reform on behalf of the Administration. **We are grateful for your support and enactment of the revised fee schedule last November that will help fund the Plan. Since the bill that passed was different from the Administration's original submission, we are working to ensure that the USPTO's strategic goals can be met, consistent with the parameters of the modified fee schedule in place for two years. We need to work creatively to achieve the gains in light of the record workload that patent system faces today.**

Like you, we are tasked with looking at patent issues from every angle. We must look at them from the perspective of the independent inventor, who may be the next Thomas Edison, to the perspective of a large, successful company that believes its innovations are being frivolously undermined by unnecessary legal obstacles. We must look at these proposals from the perspective of an economic superpower negotiating treaties to create a better intellectual property system internationally, to the perspective of the American consumer who may not care about patents but is affected greatly by the effects of our patent system.

The increasing importance of trade in IP industries to the world economy has also increased calls for substantive harmonization and cooperation among intellectual property offices. At the same time, it has put pressure on the international organizations concerned with intellectual property. As we at the USPTO are working internally to improve our systems, we are also working with our trading partners to ensure that the world IP system becomes more effective.

Developments in International Patent Law

A strong U.S. patent system is not enough for American innovators, whether in established businesses, independent entrepreneurs and start-ups, or non-profits. While patent rights are territorial, the opportunities and challenges in the international arena are incredible, both in the near- and long- term. Critics have observed that there is growing anti-IP sentiment internationally – and in some domestic circles. This sentiment has even, in some instances, spilled into the World Intellectual Property Organization (WIPO). The simplest patent harmonization efforts recently have been met with obstruction and procedural tactics. We must work hard to achieve a consensus at WIPO, and ideally, we should have every nation agree on intellectual property reforms. We cannot have a few nations obstructing the process on reforms that will benefit them and the rest of the world.

The USPTO has been successful in launching a process to bring together interested international parties to establish a work plan for progress on substantive patent law

harmonization. In February 2005, we held an inaugural meeting in the United States, which was attended by 20 nations, the European Union, and the European Patent Office. This meeting resulted in the unanimous decision to establish a technical working group for the express purpose of discussing certain areas of patent law harmonization.¹

Building on this momentum, subsequent WIPO-sponsored consultations resulted in a general statement regarding a suitable work plan for proceeding with patent law harmonization within WIPO.² Continuing work on these parallel tracks will lead us closer to immediate benefits that will inure to the patent community and patent offices worldwide. This dual approach will be encouraged for other IP-related issues as well.

However, a challenge we face is the use of Patent Cooperation Treaty (PCT) fees paid to WIPO. At WIPO, less than \$1 out of every \$3 goes to the Office of the Patent Cooperation Treaty (PCT). As a result, the United States and a handful of other developed nations effectively are the net donors to the WIPO, while the remaining 174 nations are net receivers. These net receivers are the beneficiaries of the fees Americans pay, which do not go to PCT operations.

I am happy to say we were successful in protecting against further PCT fee increases last year at WIPO. We staunchly opposed a proposal and then stopped a provision that would have raised fees another 12.7 percent more than the previous year's. This saved U.S. applicants more than \$20 million annually.

We must keep in mind that proposals exist to fundamentally change the WIPO charter and philosophy -- from one that promotes intellectual property and its protection to a more amorphous charter of "balancing" intellectual property rights. We have no quarrels with "balance," -- in fact, we believe our current system and international norms are properly balanced. But simply put, this new "balancing act" is a strategy to water down intellectual property protection, and the U.S. will fight this. Clearly, our future efforts around the world on IP issues hold even greater opportunities and challenges as we continue to promote strong, global IP protection that keeps pace with technological development.

Conclusion

I take this opportunity to reiterate to you, the Members of the Subcommittee, our commitment to ensuring that USPTO's practices and policies promote the innovation and dissemination of new technologies. While we work to improve our system by internal reform of USPTO operations, we realize that additional measures within the domain of Congress can also make invaluable contributions.

The overwhelming evidence of the history of the U.S. patent system suggests that strong intellectual property protection supports, rather than impedes, innovation. Indeed, for more than 200 years, our patent system has helped American industry flourish, creating countless jobs for our citizens. Advanced technologies have been -- and continue to be --

nurtured and developed in our nation to a degree that is unmatched in the rest of the world. In many instances, the availability of patent protection has been integral to these advancements.

In this regard, the USPTO and the Administration look forward to continuing to work with you and the Members of the Subcommittee as you develop reform legislation to ensure that the U.S. patent system remains the envy of the world.

Thank you, Mr. Chairman.

Notes

1 Statement and Participants of the Exploratory Meeting of Interested Parties Concerning the Future of Substantive Patent Law Harmonization, held February 3-4, 2005, in Alexandria, Virginia

The Participants of the Exploratory Meeting of Interested Parties Concerning the Future of Substantive Patent Law Harmonization, held February 3-4, 2005 in Alexandria, Virginia, wishing to promote and facilitate progress on certain key issues under consideration in the World Intellectual Property Organization (WIPO), agree to convene future meetings to consider:

- o substantive patent law harmonization issues, notably the Trilateral "first package," as developed by the United States Patent and Trademark Office, the European Patent Office and the Japan Patent Office and set forth in WIPO Document WO/GA/31/10; and
- o issues with regard to intellectual property and development, including proposals for a WIPO Development Agenda and proposals relating to genetic resources, with a view to seeking a common basis for further discussions in WIPO.

* The Participants agree that the following parties will be invited to participate in the future meetings: all Members of WIPO Group B, Member States of the European Union, the European Commission, Member States of the European Patent Organization, and the European Patent Office.

* The Participants further agree to have regular, intersessional meetings of subgroups to address the issues reference in Paragraph 1.

Participants were Australia, Belgium, Canada, Czech Republic, Denmark, Germany, France, Hungary, Ireland, Italy, Japan, Lithuania, Luxembourg, Netherlands, Portugal, Romania, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom, and the United States.

2 Statement and Participants of Informal Consultations in Casablanca on February 16, 2005

Statement Adopted at the End of Informal Consultations
in Casablanca on February 16, 2005

1. Following the mandate given to him by the WIPO General Assembly in September 2004, the Director General of WIPO convened informal consultations concerning future sessions of the Standing Committee of Patents (SCP) in Casablanca, Morocco, on February 16, 2005.

The consultations were **attended** by delegates from Brazil, Chile, China, France, Germany, India, Italy, Japan, Malaysia, Mexico, Morocco, Russian Federation, Switzerland, United Kingdom, United States of America, African Regional Industrial Property Organization (ARIPO), Eurasian Patent Office (EAPO), European Patent Office (EPO), African Intellectual Property Organization (OAPI) and the European Union. Dr. R.A. Mashelkar, Director General of the Council of Scientific and Industrial Research (CSIR) and Secretary of the Department of Scientific and Industrial Research in India, chaired the consultations.

2. The consultations were held in a positive spirit. The delegates strongly endorsed the importance of multilateralism, in particular, in WIPO. The consultations resulted in the development of a proposed action plan for the near future.

3. There was broad agreement that the objectives of the future work program of the SCP should be to address issues with a view to improving the quality of granted patents, thus avoiding unwarranted encroachments on the public domain, and to reducing unnecessary duplication of work among Patent Offices, which should produce benefits by making the patent system more accessible and cost-effective.

4. In order to achieve these objectives, the meeting agreed that the following six issues should be addressed in an accelerated manner within WIPO with a view to progressive development and codification of international intellectual property law: prior art, grace period, novelty, inventive step, sufficiency of disclosure and genetic resources. These issues should be addressed in parallel, accelerated processes, the first four issues (prior art, grace period, novelty and inventive step) in the SCP and the other two issues (sufficiency of disclosure and genetic resources) in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Each of the SCP and the IGC should agree on a timetable and report progress on the development of their discussions of the issues to the other.

5. The meeting underlined the importance of the continued active pursuit of discussions and work within WIPO on issues related to development and intellectual property so that a robust, effective and actionable WIPO Development Agenda could emerge.

6. The meeting recommended to the Director General of WIPO

(a) to call on Member States for proposals on the International Development Agenda for discussion at the April 2005 session of the Intersessional Intergovernmental Meeting (IIM),

(b) to convene the next session of the SCP in May 2005 to consider and endorse the objectives and work program set out above,

(c) to convene the next session of the IGC in June 2005 to consider and endorse the objectives and work program set out above, and

(d) to transmit the decisions of the above meetings to the General Assembly in September 2005 for its consideration, including a time frame for the conclusion of these issues within WIPO.

7. The meeting expressed its warm thanks and gratitude to the authorities of the Kingdom of Morocco for hosting the consultations.

The delegate of Brazil did not associate himself with the foregoing text.



NEWS RELEASE

ORRIN HATCH

United States Senator for Utah

FOR IMMEDIATE RELEASE
April 25, 2005

CONTACT: Adam Elggren (202) 224-3370

HATCH STATEMENT ON PATENTS

Washington – Senator Orrin G. Hatch today delivered the following statement before the Senate Judiciary Committee Subcommittee on Intellectual Property during a combined hearing titled, “The Patent System: Today and Tomorrow,” and “Perspectives on Patents”:

Statement of Sen. Orrin G. Hatch
before the
Intellectual Property Subcommittee
Senate Judiciary Committee
“Perspectives on Patents”
April 25, 2005

Good afternoon. Today I am pleased to chair the first hearing of the newly-created Intellectual Property Subcommittee of the Senate Judiciary Committee.

I commend Chairman Specter for his support in establishing the IP subcommittee. I also thank Senator Leahy for agreeing to serve as the Ranking Democratic member on this important subcommittee. We have always worked together in a bi-partisan fashion on intellectual property issues. For example, Senator Leahy and I, along with all Judiciary Committee members, joined together on legislation last year designed to curtail the diversion of patent fees from PTO. I have every hope and expectation that this subcommittee will attempt to continue to address IP issues on a bipartisan basis.

In this regard, I want to take just a moment to commend Senator Leahy, Cornyn and Feinstein for all their work last Congress and this Congress in securing passage of an important bill that passed the House last Tuesday – S. 167, “The Family Entertainment and Copyright Act of 2005.”

I am pleased that this important piece of intellectual property legislation has finally been sent to the President. This bill contains several provisions, including the anti-circumventing protections that Senators Cornyn and Feinstein championed in the Senate. The bill also reauthorizes the National Film Preservation Board, a matter of great interest to Senator Leahy

and many others.

Additionally, the bill contains a provision protecting certain technologies that help parents shield their families from material in motion pictures that is too graphic for young family members. This has been a matter of some interest in my home state of Utah and I am pleased that it has finally been passed by both houses of Congress. I commend Chairmen Lamar Smith and Jim Sensenbrenner and Ranking Democratic Members Howard Berman and John Conyers for their contributions in bringing this bill through the House.

Today, we will move to the patent side of the intellectual property arena. This is the first of a series of hearings that we plan to hold on patent reform to discuss in a fairly comprehensive manner some of the proposed changes to the substantive, procedural, and administrative aspects of the system that governs how entities here in the United States apply for, receive, and eventually make use of patents covering everything from computer chips to pharmaceuticals to medical devices to – I am told – at least one variety of crustless peanut butter and jelly sandwich. As the Founding Fathers made clear in Article 1, Section 8 of the Constitution, Congress is charged with *promot[ing] the Progress of Science and useful Arts, by securing to for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries*. It is my hope that today's hearing will help further that charge by encouraging an active debate on patent reform.

There is a growing consensus among those who use the patent system that reform is needed. For example, at least two of the organizations represented here today – the Business Software Alliance and the American Intellectual Property Law Association – have taken the initiative to develop discussion drafts of patent legislation, many key provisions of which have been incorporated in Chairman Smith's Committee Print over in the House. I have also received a number of other suggestions – some of them fairly broad, some very narrow – from a variety of individuals and businesses around the country on changes they would like to see made to the current patent system. I always welcome constructive suggestions throughout the legislative process.

There appears to be a high degree of agreement on some issues relating to patent reform – such as the advisability of creating a new post-grant review process. There are other areas, such as modifying the role of injunctive relief in patent litigation, where – at least based on the written testimony before us – significant differences remain. I hope that today's hearing will help to further the important debate regarding patent reform.

In order to better understand the current state of affairs of U.S. patents and the climate from which these reform proposals have emerged, we will first hear from Jon Dudas, the Undersecretary for Intellectual Property and Director of the United States Patent and Trademark Office. We welcome Undersecretary Dudas back to this hearing room.

Undersecretary Dudas will help describe the growing importance of patent protection in the increasingly inter-dependent global economy. The United States has consistently led the world in many critical area areas of technology development such as computer hardware and software, telecommunications, and biotechnology. To remain in the forefront of developing and

translating new ideas into tangible goods and services for the benefit of Americans and other consumers around the world, there must be in place an equitable and efficient patent review and protection system both here and abroad.

We should all take pride in the fact that the United States Patent and Trademark Office is widely recognized as one of the leading IP organizations in the world. Thousands of dedicated professionals at PTO are responsible for this success. But the agency faces great challenges in accommodating the ever increasing number and complexity of patent applications being filed each year. As Undersecretary Dudas will detail, U.S. patent applications have doubled since 1992, and last year the PTO issued more patents, some 173,000 patents, that it did during the first 40 years of the agency's existence.

We will also hear today where PTO stands in the implementation of its *21st Century Strategic Plan*. In addition, we will have an opportunity to discuss how PTO is responding to the key recommendations contained in the September, 2004 Department of Commerce Inspector General's Report entitled, *USPTO Should Reassess How Examiner Goals, Performance Appraisal Plans, and the Award System Stimulate and Reward Examiner Production*.

As well, I plan to explore the degree to which Undersecretary Dudas agrees, or disagrees, with the recommendations made by the National Research Council of the National Academy of Sciences in its major study, *A Patent System for the 21st Century*. We are pleased to have the distinguished co-chairs of this report on our second panel today: Dr. Mark Myers of the Wharton School of the University of Pennsylvania and Dr. Richard Levin, President of Yale University.

On our third panel we will have a collection of inventors and protectors of intellectual property. This panel includes two inventors, William Parker of Waitsfield, Vermont and Dean Kamen, who was recently inducted into the National Inventors Hall of Fame. I am pleased to have these two independent inventors before us today because it helps to emphasize that, although we lawyers have a modest role to play, the real purpose of intellectual property is to help ensure that the interests of innovators and consumers are both served.

We will also hear from David Simon, Chief Patent Counsel of Intel and Bob Armitage, General Patent Counsel of Eli Lilly. Bob is a veteran of testifying before the Judiciary Committee due to his work on improving the Schumer-McCain amendments to the Hatch-Waxman Act that were part of the 2003 Medicare Modernization Bill.

We are also particularly pleased to have with us Joel Poppen, Deputy General Counsel of Micron Technologies. While Micron is based in Boise, I understand that they have some outstanding employees and facilities in Utah. I have enjoyed working with Micron on a number of trade issues to ensure that U.S. computer chip makers are treated fairly in Asia and around the world.

Last, and by no means least, we have Mike Kirk, Executive Director of the American Intellectual Property Law Association. Dating back to his days at PTO, Mike has long been a calm, clear, and reasonable voice in all intellectual property legislation. I would also like to

recognize that there are a number of distinguished authorities on patent law present today that we were not able to invite to testify today. In particular, I would like to note the presence of Herb Walmsley of the Intellectual Property Owners Association as well as representatives from a variety of intellectual property groups here in town.

It is my hope that today's hearing will help the members of this subcommittee better understand what works well, and what should be improved, in our current patent system. Before we attempt to fashion any legislative fixes to the patent system, it is essential that we carefully identify the problems we are attempting to solve.

We have learned time and time again — the Digital Millennium Copyright Act and the American Inventors Protection Act come to mind — that it can take a lot of time-consuming and hard work to forge successful consensus on IP legislation.

I stand ready to roll up my sleeves and work with my colleagues in Congress and other affected parties on intellectual property issues.

One area where I hope we can join together on a broad bipartisan basis is working to help curtail international piracy of U.S. intellectual property. We must be vigilant in our trade negotiations to make sure that our trading partners do not merely talk the talk — they must walk the walk on enforcing intellectual property laws.

Not to put too fine a point on it, many of us in Congress are watching USTR closely to see what the agency will do in relation to IP theft in the next Special 301 Round with respect to countries such as China and Russia. While there may — I emphasize the word may — be a case to support Russia's entry into the WTO, Russia should not be permitted to become the new China when it comes to only half-heartedly enforcing laws, that some experts believe are only half-baked to begin with, intended to protect against the piracy of intellectual property. The Subcommittee plans to hold a hearing on piracy of intellectual property in the week following the next recess.

Let me close by saying that I think the fact that thirteen of the very busy eighteen members of the full Judiciary Committee have made it a priority in their already crowded schedules to join this new subcommittee speaks volumes about how important we on both sides of the aisle view intellectual property matters to the continued success and growth of the American economy and the quality of life for U.S. citizens.

I look forward to today's hearing and the future work of this new subcommittee.

Thank you.

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Statement of

Dean Kamen

President

DEKA Research & Development Corp.

Before the

Subcommittee on Intellectual Property

Committee on the Judiciary

United States Senate Washington, D.C.

On

Perspectives on Patents

April 25, 2005

Mr. Chairman, Members of the Committee, thank you for the opportunity to be here today at this important hearing. I am Dean Kamen, President of DEKA Research & Development Corp., a technology development company based in Manchester, New Hampshire that I founded in 1982. As a holder of more than 100 U.S. patents, I am pleased to speak to you today from the perspective of an inventor.

As a small businessman whose company relies heavily on intellectual property, I feel that maintaining strong patent protection for America's inventors is critical. From my perspective, some of the proposals currently being discussed – such as the weakening of injunctive relief, post-grant opposition, and the elimination of the presumption of patent validity – are extremely concerning.

Specifically, I would offer the following perspectives as the Congress considers how to maintain and improve our country's patent system:

1. The purpose of the patent system in the United States, as set forth in Article 1, Section 8, Clause 8 of the Constitution, is to "promote the progress of ...the useful arts by securing to ...inventors for limited times the exclusive rights to their ...discoveries." As President Abraham Lincoln stated, our patent system "adds fuel of interest to the fire of genius." To work correctly, the patent system must appropriately reward innovation and risk.
2. In exchange for the right to exclude others from practicing the invention for a period of years, the public gains the benefit of the technical knowledge contained in the patent disclosure. The public also gains when the technology enters the public domain at the end of the patent term.
3. A strong patent system, at its core, must ensure that the U.S. Patent and Trademark Office issues patents of the highest possible quality. To accomplish this, patent applications must be examined effectively by highly qualified examiners, using the best available technology and prior art. Any patent reform must fundamentally focus on ensuring patent quality prior to the issuance of the patent.
4. It is my understanding that one reason this examination process is in need of improvement is because funding for the U.S. Patent and Trademark Office has not kept up with the increased number of patent applications being filed. Ending the diversion of patent fees to other parts of the government would certainly help address this underfunding. With the proper funding, I am confident that the Director of the U.S. Patent and Trademark Office, Jonathan Dudas, could find ways to hire, train, retain and reward examiners with the requisite credentials to solve the quality problem at its roots. With state of the art search tools and access to the world's technical literature at their fingertips, along with proper training, supervision and adequate time to do a quality job, many of the real and perceived problems with the patent system should fade away.
5. I fear that some of the patent reform measures currently under discussion are not only unnecessary to address the issues that exist in our patent system today, but have the very real potential to create substantially worse problems. Fundamentally our existing patent system is not broken. It is uncontested that a vast majority of the patents issued by the U.S. Patent and Trademark Office are sound. While we should strive to further improve

patent quality, we should not allow the limited number of cases of poorer quality patents to drive changes to the patent system that has served this country well for more than 200 years. Before enacting the most dramatic change to our patent laws in the past 50 years, I would suggest that Congress carefully evaluate whether the various provisions that are being proposed will indeed benefit the economy and support innovation.

6. One of the areas of consideration for patent law reform that gives me particular concern is the weakening of injunctive relief. Particularly troublesome is the elimination of the rebuttable presumption of irreparable harm when seeking a permanent injunction after a patent has been found to be valid and infringed. I believe that reversing the burden of proof to obtain a permanent injunction will have catastrophic consequences in our patent system and is particularly problematic for independent inventors.
 - It is a fundamental principle of United States patent law to recognize patents as forms of property (like real property). That is, the holder of a valid patent has a right to exclude others from trespassing on that owner's private property.
 - The Constitutional right to exclude others is properly enforced by using the mechanism of a permanent injunction. It is important to note that a permanent injunction can only be granted after a patent is found to be valid and infringed.
 - Parties may be less likely to settle disputes if money is the only risk or penalty that party would face for trampling on the valuable property rights of others. Reversing the presumption of irreparable harm, therefore, may discourage parties from settling their disputes, thus prolonging and increasing the costs of litigation.
 - Weakening the standard for granting permanent injunctions would be tantamount to adopting compulsory licensing. The United States has fought hard to eliminate these types of compulsory licensing schemes in the international arena through the TRIPS agreement.
7. Finally, to require a patent owner to personally manufacture and sell products covered by his or her patent before being entitled to an injunction would diminish the individual inventor's incentive to invent. Indeed, the individual inventor is seldom in the best position to personally commercialize his or her invention. For example, my company focuses on doing what we do best – creating innovative technology – and then seeks to partner with established corporations in the relevant field to allow them to do what they do best – manufacture, market, and sell these products. This business practice is entirely consistent with the fundamental purpose of patents, to promote the benefits of technology, by getting these innovative products, as quickly and efficiently as possible, into the hands of the people who need them.

Conclusion

As innovation becomes ever more important to America's global competitiveness, a strong patent system is more important than ever. I strongly urge you to be extremely hesitant to move any legislation that could undermine an enduring component of the economic system that has made America the envy of the world for more than two centuries.



Statement of

**Michael K. Kirk
Executive Director
American Intellectual Property Law Association**

Before the

**Subcommittee on Intellectual Property
United States Senate
Washington, D.C.**

On

Perspectives on Patents

April 25, 2005

Mr. Chairman:

I am pleased to have the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) on the need to improve the United States patent system and the legislative reforms AIPLA proposes to address this need. AIPLA expresses its appreciation to you for holding this hearing to identify the important problems confronting the U.S. patent system and to identify appropriate solutions to address these problems.

AIPLA is a national bar association of more than 16,000 members engaged in private and corporate practice, in government services, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Since our members represent inventors before the PTO, as well as both plaintiffs and defendants in patent litigation, we have a keen interest in reforms that further an efficient, effective, and balanced patent system.

The Need for Reform

The U.S. patent system has, in certain respects, functioned remarkably well. Its successes today are in significant part attributable to a number of reforms that have been made by Congress during the past 25 years. The creation of the Federal Circuit, the passage of the Patent Law Amendments Act of 1984, the adoption of reexamination, and the enactment of the American Inventors Protection Act have made the patent system more open and much stronger as an incentive to invest in innovation. However, there are

aspects of the U.S. patent system that are not working well today. Over the past decade, some of these elements of the patent system have, in fact, come to work less well.

This conclusion is shared by others. Two recent studies of the U.S. patent system have produced lengthy reports that have largely come to the same conclusion. The Federal Trade Commission report, (*To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Report by the Federal Trade Commission, (October 2003)), found that while most of the patent system works well, some modifications are needed to maintain a proper balance between competition and patent law and policy. The FTC made ten recommendations that focused on tuning the balance between patent owners' rights to effective exclusivity in valid patents and the public's right to be free from the competition-limiting effects of invalid patents.

The report of the National Academies of Sciences' Committee on Intellectual Property Rights in the Knowledge-Based Economy (NAS) was published just one year ago, in April 2004. Like the FTC effort, it was the culmination of a multi-year study of the patent system. The NAS report found that the U.S. patent system played an important role in stimulating technological innovation by providing legal protection to inventions and by disseminating useful technical information. Moreover, with the growing importance of technology to the nation's well-being, it found that patents are playing an even more prominent role in the economy. It concluded with seven principal recommendations to ensure the vitality and improve the functioning of the U.S. patent system, several of which overlap those made by the FTC.

AIPLA has also studied the effectiveness of the patent system. Former AIPLA President Rick Nydegger recognized the need to review the functioning of the patent

system almost two years ago and established a Special AIPLA Committee on Patent Legislative Strategies in an effort to provide more concrete and coordinated ideas for needed reforms to the patent law. The Special Committee was co-chaired by two other former AIPLA Presidents, Don Martens and Bob Armitage, and its membership was drawn from a diverse cross-section of AIPLA members. It included former senior officials of the United States Patent and Trademark Office, a retired federal district court judge, some of the nation's leading patent litigators including Past Presidents of our Association, and in-house IP counsel drawn from several industry sectors.

In efforts paralleling that of our Special Committee on Legislative Strategies, AIPLA undertook an exhaustive analysis of the recommendations in both the FTC and NAS reports and offered replies. These parallel and sometimes intersecting efforts stimulated us to take a closer look at a number of issues and push to further develop and refine concrete proposals for reforms.

After developing these reform proposals that were ultimately approved following several meetings of AIPLA's Board of Directors, we concluded that it would be highly desirable to take them to a broader public. After discussions with the officials responsible for developing similar recommendations in the FTC and NAS reports, we agreed with FTC and NAS to jointly sponsor three "Town Hall" meetings across the country. These were open forums to explain to all stakeholders the proposed reforms to the patent system and to allow them to offer their reactions and suggestions. We have planned a fourth and final meeting for Washington, D.C., on June 9. This final meeting will allow us to distill the work of the three previous meetings.

These parallel efforts by three quite different organizations with quite distinct missions are especially striking because of their similar diagnosis of what needs improving in the patent system and, especially as between AIPLA and NAS, the convergence in the recommendations for doing so.

For any organization putting together an effort at patent law reform, a critically most important task is to make a clear separation between what is right with our patent laws – and does not requiring tinkering – and what is wrong with our patent laws – and, therefore, should be the subject of focused attention. Where, for example, could reforms have the biggest benefits for all users of the patent system? What is actually ready for reform today, because a sufficient consensus already exists or could be developed, or because sufficient study and scholarship have taken place? And where might more study and reflection be needed before forging ahead with changes to the patent system? Our assessment is that our work with the NAS and the FTC in large part validates our reform proposals as a possible way forward to near-term patent reforms.

We have been especially mindful that patent law reform is never easy because of the diversity of the constituencies with a stake in the patent system. However, AIPLA believes that successful patent law reform has been and always will be an effort at inclusion. This comes naturally to us because our membership reflects the diversity of stakeholders in the patent system – clients of our members both obtain patents and challenge patents.

Our notion of inclusion means, therefore, that reforms work to make a better patent system not only for inventors with adequate resources – more often than not inventors connected with so-called “large entities” such as corporations – but also for the

least financially able inventors – which includes many “independent inventors,” not-for-profit institutions, and small businesses.

Another equally important aspect of inclusion relates to the manner in which the patent system works to protect the interests both of those who seek patents, those who challenge patents, and the public. The patent system works best when standards for patentability are rigorously applied and mistakes – that will inevitably be made when patents are issued that should not have – can be readily corrected. While much emphasis is understandably placed on making the patent system work better for inventors, a fair and balanced patent system needs to work equally well when a member of the public seeks to have a mistake made in issuing a patent quickly and inexpensively corrected.

Funding: An Essential Prerequisite for Patent Law Reform

Before discussing our legislative proposals for patent law reform, we cannot overlook the most fundamental problem in need of a solution – adequate and stable funding and operational flexibility for the PTO. Any careful study of the U.S. patent system today would reach this conclusion – indeed, both the NAS and FTC recommended providing adequate funding for the PTO. The Office must be afforded the resources and capabilities to deal with a workload that has grown dramatically – both in size and complexity. As patent rights have become more important, it has become much more important that the quality of PTO’s work improve. Important patents take too long to issue. Technologies new to patenting require building new capabilities for examining them, sometimes almost from scratch.

The need for a more efficient and effective PTO will require adequate funding, but it will also require long-range planning, oversight, and accountability. AIPLA

supported the PTO's development of the Strategic Plan requested by Congress. For the Office to be able to build new capabilities, improve its quality, become more efficient, and serve all its constituencies, it must anticipate, plan for, and invest in new capabilities. This requires on-going efforts at long-term planning that must include long-range financial and operational planning.

Of course, PTO planning and Congressional oversight will mean nothing without adequate funding. Many of the reforms that AIPLA and others are proposing will require the PTO to play a greater role in the overall patent system. AIPLA is dedicated to working with the Congress, both this Committee and the Appropriations Committee, to secure a financing structure that will allow the patent law reforms which we propose to be achieved. However, we cannot emphasize enough the importance of this goal: the most significant patent law reforms absolutely depend on the PTO having the financing and operational flexibility to carry them out effectively and efficiently.

AIPLA's Proposed Patent Law Reforms

Turning now to substantive proposals for patent law reform, AIPLA believes that the time is right for Congress to adopt a coordinated and interrelated set of reforms to the patent system as recommended by the NAS and which we support:

- Adopt a first-inventor-to file system with an objective definition of "prior art" – the information used to determine if an invention is new and non-obvious.
- Limit or eliminate the subjective elements in patent litigation, i.e., "inequitable conduct," "willful infringement," and "best mode."
- Complete the desirable legislative enhancements originally proposed in what became the American Inventors Protection Act.

- Adopt a fair and balanced post-grant opposition system that takes advantage of the elimination of the subjective elements in patentability criteria that accompany adoption of the first-inventor-to-file principle.

Adopt first-inventor-to-file system and simplify patent law determinations of validity

AIPLA supports the principle that the first inventor to file an application for patent containing an adequate disclosure (35 U.S.C. §112) of an invention should have the right to patent the invention. This change in U.S. patent law would bring a much needed simplification of the process and reduce the legal costs imposed on U.S. inventors. It would also improve the fairness of our patent system, and would significantly enhance the opportunity to make real progress toward a more global, harmonized patent system in general.

The current system is based on complex proofs of invention and is fundamentally unfair to independent inventors and small entities due to its costs and complexities. It frequently does *not* award patents to the first to invent. It uniformly awards patents to the first-inventor-to-file for a patent except where sufficient, corroborated invention date proofs can be marshaled to demonstrate that a second-to-file inventor can overcome the *presumption* currently afforded under our patent law in favor of the first inventor who filed.

Moreover, the expense and complexity of the first-to-invent system mean that an inventor can be first to make the invention and first to file a patent application, but still forfeit the right to a patent because the inventor cannot sustain the cost of the “proof of invention” system. According to AIPLA’s 2003 Economic Survey, the median cost to an inventor in a simple, two-party interference is \$113,000 to complete the preliminary

phase (discovery) and over \$300,000 to the final resolution. Costs of this magnitude place independent inventors, small entities and universities at a clear disadvantage.

This disadvantage has been heightened in recent years by the new right of foreign-based inventors to introduce invention date proofs. While a decade ago a U.S.-based inventor might have had some advantage because of the bar against relying on a foreign date of invention, this provision of U.S. patent law was outlawed by TRIPS. Thus, independent inventors, small entities and universities are now also subject to this kind of cost disparity from attacks brought by foreign applicants and parties.

Former PTO Commissioner Gerald J. Mossinghoff presented empirical data at our Town Hall meetings based on his earlier research. See Gerald J. Mossinghoff, *The First-to-Invent System Has Provided No Advantage to Small Entities*, 88 J. Pat & Trademark Off. Soc’y 425 (2002). His data demonstrated conclusively that independent inventors, whose right to patent their inventions depended on their ability to prove that they were “first to invent,” managed to lose more often than not. In an April 15, 2005 Working Paper published by the Washington Legal Foundation, Mossinghoff’s most recent data suggests that the rate of loss by independent inventors has only accelerated over the past several years (Gerald J. Mossinghoff, *Small Entities and the “First to Invent” System: An Empirical Analysis*, <http://www.wlf.org/upload/MossinghoffWP.pdf>).

An analysis by Professor Mark A. Lemley and Colleen V. Chien reaches an even more stunning conclusion. The Lemley and Chien findings suggest that the current first-to-invent contests “are more often used by large entities to challenge the priority of small entities, not the reverse. This evidence further supports Mossinghoff’s conclusion that the

first to invent system is not working to the benefit of small entities.” See *Are the U.S. Patent Priority Rules Really Necessary?*, 54 Hastings Law Journal 1 (2003).

Given the cost, complexity and demonstrable unfairness imposed by the present first-to-invent system, it is clear that a change to a first-inventor-to-file system in our patent law is justifiable simply on grounds that it is the “best practice.” With the adoption of a first-inventor-to-file rule, 35 U.S.C. §102 can be greatly simplified. Prior art would no longer be measured against a date of invention: if anticipatory information was reasonably and effectively accessible before the earliest effective filing date of a patent application, no patent issues. Similarly, the question of whether an inventor “abandoned” an invention would no longer be relevant. And, of course, proofs of conception, diligence, and reduction to practice become irrelevant.

A first-inventor-to-file system will also clearly benefit large and small businesses. It will eliminate the present delays and uncertainty associated with resolution of interferences which complicate business planning. In addition, it will remove the potential cloud over important inventions that will always be present in a first-to-invent system.

Limit the subjective elements of patent litigation

- *“Inequitable conduct”*

The National Academies singled out the “inequitable conduct” defense as one of three so-called “subjective elements” in patent litigation that should be limited or eliminated. Inventors and patent owners need for Congress to address the issue of the “inequitable conduct” unenforceability defense.

The defense of inequitable conduct applies when the patent applicant has made a material misstatement or omission with intent to deceive the PTO. Examples of conduct punishable as inequitable conduct might include the intentional failure to disclose a known prior art reference (unless cumulative), burying a material reference in a large bundle of other references, or making false or misleading statements to the PTO. Despite the salutary intent of the doctrine, it has become an overused weapon in patent litigation. As noted in *Burlington Industries v. Dayco Corp.* 849 F.2d 1418 (Fed. Cir. 1988), “[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”

The heart of the APLA proposal for addressing the use of the “inequitable conduct” defense in patent litigation is to limit – not eliminate - the ability of an accused infringer to plead this defense to clear cases of common law fraud. But let me be clear: our proposal would not lessen the duty of candor and good faith – it would more effectively enforce it. Thus, we propose to allow this defense to be pled only in the circumstance where the court has invalidated a claim and the accused infringer has a reasonable basis for alleging that, absent the fraudulent misconduct attributable to the patent owner (“but for” the conduct of the patent owner), a reasonable patent examiner would not have allowed the invalidated claim to issue as part of the patent. Where such conduct is proven, a fraud has occurred and the patent would be unenforceable. Thus, the APLA proposal would return the “inequitable conduct” defense to its equitable roots. A patent owner who had engaged in a fraud to secure an invalid claim would not be able to enforce the patent – the patent owner’s “unclean hands” would preclude such enforcement.

After considering a number of alternative proposals, we came to the conclusion that other possible misconduct by the patent owner that does not rise to the level of fraud – that is, misconduct that would not have resulted in an examiner allowing a claim even if the omission or misstatement had not occurred – should be referred by the court back to the PTO. We propose that Congress codify the duty of candor and good faith and give the PTO the authority to administer that duty where questionable misconduct is uncovered during patent enforcement proceedings. Like other agencies, Congress should look to the PTO to enforce its own rules and charge it with the responsibility for doing so. No agency of government undertaking work of crucial importance to the nation should have rules mandating high standards of conduct for those appearing before it and not have responsibility, resources, and capabilities for administering and enforcing those rules. This would allow the Office – as part of its control over the duty of candor and good faith – to determine whether or not the allegations merited investigation and sanction.

Giving the PTO authority over the duty of candor and good faith means that the Office could address the dilemmas faced by those representing clients who – justifiably and consistently – have opposed efforts by the Office to mandate more meaningful disclosures of information. Such more meaningful disclosures could clearly drive the efficiency and accuracy of the patent examination process – for example, by specifying the contents of statements to be submitted regarding the potential relevance of prior art. Today, if such statements are offered, they are fodder for the “inequitable conduct” defenses raised in patent litigation. Placing the PTO in control of the duty of candor and good faith would allow the creation of “safe harbors” for applicants satisfying enhanced

disclosure requirements which could not later be used as grounds for an allegation of inequitable conduct.

Giving the PTO such authority could also address an AIPLA concern for a post-grant opposition procedure, namely, that the duty of candor and good faith should meaningfully apply to opposers. An opposer that raises an issue of unpatentability should be no more free to mislead or misrepresent the facts in that proceeding than an inventor or patent owner in a PTO proceeding. This is a hole in the duty today with respect to reexamination that could be filled by giving the PTO such authority.

We propose, therefore, that Congress adopt a mechanism that would authorize the PTO to investigate misconduct by opposers and third parties who request reexamination and to impose civil monetary sanctions on patentees and disbarment of their attorneys. In addition, where false statements have been made, the mechanism for sanctioning misconduct should include a mechanism for referrals to the Criminal Division of the Department of Justice.

We believe that such proceedings by the PTO – where the Office elects to proceed after reviewing a referral from a court – would be relatively rare events, but nonetheless a much more effective deterrent to misconduct than the current unenforceability defense. The current reliance on the courts for “enforcement” of the duty is problematic because it can lead to the punishment of benign deeds and the failure to punish bad deeds. The ultimate ineffectiveness of the inequitable conduct defense today is probably best illustrated by the fact that it is raised and litigated in almost every important patent case, but is rarely successful.

- *“Willful infringement”*

NAS also recommended that the doctrine of willful infringement be eliminated from patent litigation. It observed that the question of willful infringement involves an issue of intent that produces a significant discovery burden, introduces an element of substantial uncertainty, and complicates much patent infringement litigation. While APLA does not recommend its elimination, we agree that Congress should act to contain charges of willful infringement.

During the hearings conducted by the FTC, it was revealed in testimony that some companies forbid their engineers from reading patents for fear that such acts might be used by a patentee to allege that the company willfully infringed the patent. As reported by the FTC, “the failure to read a competitor’s patents can jeopardize plans for a noninfringing business or research strategy, encourage wasteful duplication of effort, [and] delay follow-on innovation...” (FTC Report, Chapter 6, page 29). This fear, whether well founded or not, forcefully demonstrates that the law on willfulness has effectively undermined the Constitutional purpose of the patent system, i.e., to promote the progress of the useful arts. In practice, exposure to a claim of willfulness is not limited to cases of knowing, intentional infringement. Knowledge of a patent, coupled with a decision to engage in or continue conduct later found to be infringing, may be enough to result in treble damages.

Moreover, willfulness is asserted in most cases. Professor Kimberly A. Moore, George Mason University School of Law, conducted an empirical study of willfulness, looking at patent infringement cases that terminated during litigation from 1999–2000. Professor Moore found that willful infringement was alleged in over 92% of the cases,

observing that her “results suggest that willfulness claims are plaguing patent law. It seems unlikely that in 92% of the cases, the patentee had sufficient factual basis at the time the complaint was filed to allege that the defendant’s infringement was willful.” See *Empirical Statistics on Willful Patent Infringement*, 15 Fed. Cir. B.J. 227 (2004),

Additional problems arise from the Federal Circuit’s opinion in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F2d 1380 (Fed. Cir. 1983). The decision speaks of an accused infringer having an affirmative duty to exercise due care to determine whether or not he is infringing once given notice of a another’s patent, including the duty to seek and obtain competent legal advice from counsel. This leads to hundreds of thousands of dollars spent by company after company on opinions of counsel as insurance against a finding of willful infringement. This perceived obligation also leads to problems with attorney disqualification since the attorney giving the opinion will be called as a witness during the litigation. As a result, a company’s chosen counsel cannot act as both its counselor and its trial attorney. Some states, such as the state of Virginia, do not even allow the attorney trying the patent infringement case to be in the same law firm as the attorney who drafted the infringement opinion. Complicated issues involving waiver of attorney-client privilege further exacerbate the matter.

These difficulties were not obviated by the en banc reconsideration of *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.* 383 F3d 1337 (Fed. Cir. 2004). While the Court did rule that it is inappropriate for the trier of fact to draw an adverse inference with respect to willful infringement when a defendant has not obtained legal advice or invokes the attorney-client privilege, the decision leaves untouched the duty of due care and the circumstances which give rise to such duty.

AIPLA would retain the concept of willful infringement, but would limit it to apply only where the infringer is truly a bad actor. Of course, every successful patentee will still receive damages adequate to compensate for the infringement, together with interest and costs as fixed by the court. In general, however, absent copying of a patented invention with knowledge that it was patented, we believe there should be no finding of willful infringement unless the patent owner has provided to the infringer a detailed written notification of the specific patent claims infringed and the infringing products and processes.

We further believe there should be no finding of willful infringement if an infringer can establish that, once it had received notice, (1) it obtained competent advice of counsel that there was no infringement on the grounds of invalidity, unenforceability or non-infringement, and (2) it reasonably relied upon such advice. In cases of the intentional copying of an invention knowing it to be patented, the informed good faith belief of the alleged infringer must exist prior to the time the alleged infringing activity begins.

Finally, we believe that the absence of an opinion of counsel should not create an inference that the infringement was willful and that mere knowledge of a patent should not be the basis for enhanced damages.

- *“Best mode”*

The third subjective element in patent litigation that NAS recommended for elimination is the requirement to disclose the “best mode.” Section 112 of the Patent Act requires that an application “set forth the best mode contemplated by the inventor of carrying out his invention.” To enforce this requirement, courts inquire whether the inventor, at the time of filing, knew of a mode of practicing the invention that the

inventor believed was better than that disclosed in the application. This test is obviously subjective, focusing on the inventor's state of mind at the time an application was filed.

Because the defense depends on historical facts and because the inventor's state of mind usually can be established only by circumstantial evidence, litigation over this issue—especially pretrial discovery—can be extensive and time-consuming. Further, the best mode requirement provides only a limited incentive for a patentee to disclose more information than is required by the written description and enablement provisions of 35 U.S.C. §112. Given the cost and inefficiency of this defense and its limited incentive to provide additional disclosure to the public, the NAS report recommended its elimination. AIPPLA endorses this change. We support and would retain the requirements in current law that every patent application must provide the public a full description of the invention (i.e., the so-called “written description” requirement) and fully enable the practice of the invention the inventor seeks to patent (i.e., the so-called “enablement” requirement). However, we would remove the problematic and subjective requirement, first introduced into the patent law in the 1952 Patent Act, that the inventor additionally include in the patent application the mode the inventor subjectively contemplated to be the best as of the day that the application was filed.

Enhancements to the American Inventors Protection Act

There are other important parts of the patent law that we believe should be addressed to complete the reforms needed for the patent system. Moving to a first-inventor-to-file system suggests that some changes should be made to the prior user defense to patent infringement. In addition, we believe that the patent law should expressly codify that the right to patent is the inventor's right. This fundamental right is

captured in the description of the priority system we propose: first-inventor-to-file. This right of the inventor is well understood in the laws of other countries – only the inventor has the right to a patent. The inventor can transfer this right through assignment if desired, but no one can take the invention and obtain a valid patent merely by filing the first application.

Finally, AIPLA believes that the PTO should publish all pending applications for patent 18-months after their initial filing. This would make the patent system more transparent and allow the public to make earlier determinations of whether an invention is novel and non-obvious on the basis of all prior art. It would also allow the public to better gather evidence for submission in the post-grant opposition proceeding which AIPLA supports and to which I now turn.

Adopt a fair and balanced post-grant opposition system

With the adoption of a first-inventor-to-file system and the related prior art simplification, a truly effective post-grant opposition procedure can be adopted to provide the public a mechanism to promptly correct mistakes made by the PTO in issuing patents. To encourage the public to act promptly, we believe that an opposition request should be made no later than nine months after a patent has issued. We do not view oppositions as an alternative to litigation. These procedures should allow the public to correct improvidently granted patents – patents with claims that are too broad or patents that the PTO should not have granted at all. After the initial period of nine months has passed and no opposition has been filed, patentees should enjoy a “quiet title” without the fear of later administrative challenges, except for the limited reexamination procedure.

Consistent with this approach, for an opposition brought within this nine month

window from grant, an opposer should have the burden of proving the invalidity of a claim by a preponderance of the evidence. Also consistent with this approach, we would retain the standard of “clear and convincing evidence” that applies in a patent infringement lawsuit or a declaratory judgment action seeking to invalidate a patent claim. In this way, the procedure strikes a balance – encourage the public to promptly eliminate questionable patents without unduly undercutting the patentee’s right to benefit from his invention.

As noted above, a key feature of the post-grant opposition system that we propose is that the PTO would be able to correct all mistakes made in the patent examination process. We refer to this as an “all issues” opposition, that is, a proceeding in which, unlike current reexamination proceedings, a challenger can raise all of the legal issues related to patentability. The predicate for such an “all issues” opposition is the adoption of a “first-inventor-to-file” system and related changes to the definition of prior art. Eliminating the need to consider evidence of the date on which work was actually started and completed by the inventor is a critical reason for coupling the adoption of the first-inventor-to-file principle to a post-grant opposition proceeding. The feasibility and effectiveness of the post-grant opposition proceedings would be enhanced by the removal of this otherwise complicating factor. Issues such as the inventor’s forfeiture of the right to patent through some secret commercial use or private offer for sale would be eliminated. So also would issues of “abandonment” of the invention. As previously discussed, the elimination of the requirement to disclose the “best mode” would mean that this subjective element would not complicate the proceeding and add unnecessarily

to its costs. Thus, the issues that would necessitate significant discovery – and thereby unduly complicate and increase the costs of an opposition – would vanish.

Conclusion

The U.S. patent system continues to be an essential driver of our nation's economic and technological success, but there is a growing consensus that it is in need of adjustment. The NAS and FTC have reached this conclusion. The Intellectual Property Law Section of the American Bar Association, the Intellectual Property Owners Association, the Biotechnology Industry Organization and AIPLA are generally agreed on the adjustments that need to be made.

We now have an opportunity – indeed, an obligation – to prepare the U.S. patent system for the 21st Century. The reforms that AIPLA has proposed will, we believe, achieve this goal.

We commend you, Mr. Chairman and Senator Leahy, for your continuing leadership in striving to improve our intellectual property system. The AIPLA looks forward to working with you, the other Members of the Subcommittee, and your able staffs to assist you in any way we can.

**STATEMENT OF SENATOR PATRICK LEAHY,
RANKING MEMBER, SUBCOMMITTEE ON INTELLECTUAL PROPERTY
“THE PATENT SYSTEM TODAY AND TOMORROW”
APRIL 25, 2005**

Today the Intellectual Property Subcommittee begins its public examination of the myriad issues faced by our patent system. The spirit of American innovation has made the United States the world's leader in intellectual property. Yet the expressions of American innovation – in the form of patented goods and processes – are only as good as the system that fosters and protects innovation.

I share the growing concern about our patent system's ability to address the many challenges it faces. I had looked forward to hearing from Jonathan Dudas, the Undersecretary for Intellectual Property and Director of the U.S. Patent and Trademark Office, at a hearing last Thursday. That hearing was cancelled at the last minute, and I am grateful that Mr. Dudas was gracious enough to rearrange his schedule to be with us this afternoon. We worked with Mr. Dudas to get him confirmed and before that when he staffed Republican leadership in the House and on the House Judiciary Committee. I look forward to continuing our collaboration as we tackle the patent system in the 21st Century.

I am also very pleased to welcome President Richard Levin of Yale University and Professor Mark Myers from the Wharton School of Business. They are the authors of the acclaimed National Academy of Sciences report on patent reform, and I have no doubt that their continued assistance in this project will be most useful.

The size of the project we are undertaking seems to be reflected in the number of witnesses we have at this hearing, and I do want to thank all the witnesses – people who actually live with the intricacies of our patent system every day – for appearing today. Let me draw attention to one of those witnesses, for it is particularly fitting that in discussing creativity and innovation we have with us someone who we know understands both and is a Vermonter to boot. I thank Bill Parker for traveling to Washington today to share his thoughts with us as an inventor and a spokesperson for inventors. He is part of our wonderful tradition of invention, exemplified by the fact that the first U.S. patent issued, and signed by George Washington, was to a Vermonter.

In 2002, the House and Senate directed the Patent and Trademark Office to develop a five-year plan, the result of which was the PTO's *21st Century Strategic Plan*, designed to modernize, expedite, and improve the process by which patent applications are processed. Parts of that plan are being implemented, and last year I supported a compromise in the Appropriations Committee that will – for one year – prevent PTO user fees from being

diverted to other government programs. I am interested in hearing more from our witnesses about the implementation of the PTO's plan, but I am also very interested in discussing the proposals we have all been hearing that suggest improvements to the quality of the patents the PTO is issuing.

We know that the PTO faces a Herculean task. The volume of patent applications has increased roughly three-fold since the 1980s. The PTO receives more than 350,000 patent applications annually, and the office approved 187,000 applications in 2004 alone. That works out to more than 500 approved patents *daily*. Some say that the high number of approved patent applications is itself a concern. When non-innovative inventions are patented, some patent-holders fear they will spend more time litigating than they do innovating as a result of predatory tactics. This is a real problem, and we ought to explore ways to alter the patent examination process in order to allow for patent challenges before costly, highly technical litigation is required.

In this vein, I am especially interested in the suggestions that we find ways to allow outsiders with prior art to present information at the examination stage and also that we look into the need for improved post-grant review procedures. With careful safeguards, both suggestions may help reduce unnecessary and costly litigation.

At the same time, we are hearing calls to reform the very ways in which these cases are being litigated. One criticism I have heard is that the standards which courts use to determine whether a patent violation is "willful" has been applied in a way that encourages patent holders to wear blinders to what others invent. We have also heard about abusive litigation practices of "patent trolls," described to me as companies that neither invent anything new nor produce anything at all, but simply acquire patent rights and then push the bounds of their patents, suing patent holders who actually do innovate. I am interested in hearing more about these concerns, as well as proposed solutions from our witnesses.

The concerns I mention are just a few of the many we have heard about, and I am pleased that patent reform ranks high on the legislative agenda of the 109th Congress. Today marks the first hearing of this newly-formed subcommittee and I can think of no better issue to kick off our work this year than patent reform.

As we get started, I look forward to working with the Chairman and other members of the Subcommittee. Last week the House finally granted final passage to the Family Entertainment and Copyright Act. This legislative package was sponsored by a number of us, including Senators Hatch, Feinstein, Cornyn and myself. We approved it last year and passed it, again, in February of this year. Chairman Hatch and I worked cooperatively on that legislative package last year with the result that it has now been enacted by the Congress. The Family Entertainment and Copyright Act is an example of a legislative package built through bipartisan compromise. I look forward to additional legislative accomplishments through this Subcommittee, as we proceed in a bipartisan manner.

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A PATENT SYSTEM FOR THE 21ST CENTURY

Statement of

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and

Mark B. Myers, Ph.D.
Wharton School
University of Pennsylvania

Co-Chairs

Committee on Intellectual Property Rights in the Knowledge-Based Economy
Board on Science, Technology, and Economic Policy
Policy and Global Affairs Division
National Research Council
The National Academies

before the

Committee on the Judiciary
United States Senate

April 25, 2005

Good afternoon, Mr. Chairman, Senator Leahy, and members of the committee. We are Richard Levin, President of Yale University, and Mark Myers, Wharton School of the University of Pennsylvania (formerly, Xerox Corporation), co-chairs of the Committee on Intellectual Property Rights in the Knowledge-Based Economy of the National Research Council. The Research Council is the operating arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology.

Although most Academy studies are conducted in response to an agency's or a congressional request, the study we will describe was initiated by the Council's Board on Science, Technology, and Economic Policy (STEP), because it recognized that the bottleneck pace of technological change across many industries was creating stresses in the patent system that needed to be examined to ensure that it continues to be a stimulus to innovation and does not become an impediment to it.

Since 1980 a series of judicial, legislative, and administrative actions have extended patenting to new technologies (biotechnology) and to technologies previously without or subject to other forms of intellectual property protection (software and business methods), encouraged the emergence of new players (universities), strengthened the position of patent holders vis-à-vis infringers domestically and internationally, relaxed other restraints on the use of patents (antitrust enforcement), and extended their reach upstream from commercial products to scientific research tools and materials.

As a result, patents are being more zealously sought, vigorously asserted, and aggressively enforced than ever before. There are many indications that firms in a variety of industries, as well as universities and public institutions, are attaching greater importance to patents and are willing to pay higher costs to acquire, exercise, and defend them. The workload of the U.S. Patent and Trademark Office has increased several-fold in the last few decades, to the point that it is issuing approximately 100 patents every working hour. Meanwhile, the costs of acquiring patents, promoting or securing licenses to patented technology, and prosecuting and

defending against infringement allegations in the increasing number of patent suits are rising rapidly.

In spite of these changes and the obvious importance of patents to the economy, there had not been a broad-based study of the patent system's performance since the Depression. Accordingly, the National Research Council (NRC) assembled a committee that includes three corporate R&D managers, a university administrator, three patent holders, and experts in biotechnology, bioengineering, chemicals, telecommunications, microelectronics, and software, as well as economists, legal scholars, and practicing attorneys. This diversity of experience and expertise distinguishes our panel from nearly all previous commissions on the subject, as does our study process. We held conferences and public hearings and we commissioned our own empirical research. The committee's report, *A Patent System for the 21st Century*, released a year ago, provides a thoroughly researched, timely perspective on how well the system is working.

High rates of technological innovation, especially in the 1990s but continuing to this day, suggest that the patent system is working well and does not require fundamental changes. Nevertheless, the committee was able to identify five issues that should and can be addressed now.

First, maintaining consistent patent quality is important but difficult in fast-moving fields. Over the past decade, the quality of issued patents has come under frequent sharp attack, as it sometimes has in the past. One can always find patents that appear dubious and some that are even laughable – the patent for cutting and styling hair using scissors or combs in both hands. Some errors are unavoidable in a system that issues more than 160,000 patents annually, and many of those errors will have no economic consequence because the patents will not be enforced. Still, some critics have suggested that the standards of patentability have been lowered by court decisions. Other observers fault the USPTO's performance in examining patent applications, variously attributing the alleged deterioration to inadequate time for examiners to do their work, lack of access to prior art information, perverse incentives to grant rather than reject patents, and inadequate examiners' qualifications.

Because the claim that quality has deteriorated in a broad and systematic way has not been empirically tested, conclusions must remain tentative. But there are several reasons to suspect that more issued patents are substandard, particularly in technologies newly subject to patenting. One reason to believe that quality has suffered, even before taking examiner qualifications and experience into account, is that in recent years the number of patent examiners has not kept pace with the increase in workload represented by the escalating number and growing complexity of applications. Second, patent approval rates are higher than in some other major nations' patent offices. Third, changes in the treatment of genomic and business method applications, introduced as a result of criticisms of the quality of patents being issued, reduced or at least slowed down the number of patent grants in those fields. And fourth, there does appear to have been some dilution of the application of the nonobviousness standard in biotechnology and some limitations on its proper application to business methods patent applications. Although quality appears to be more problematic in rapidly moving areas of technology newly subject to patenting and perhaps is corrected over time, the cost of waiting for an evolutionary process to run its course may be too high when new technologies attract the level of investment exhibited by the Internet, biotechnology, and now nanotechnology.

What are the costs of uncertainty surrounding patent validity in areas of emerging technology? First, uncertainty may induce a considerable volume of costly litigation. Second, in the absence of litigation, the holders of dubious patents may be unjustly enriched, and the entry of competitive products and services that would enhance consumer welfare may be deterred. Third, uncertainty about what is patentable in an emerging technology may discourage investment in innovation and product development until the courts clarify the law, or inventors may choose to incur the cost of product development only to abandon the market years later when their technology is deemed to infringe. In sum, greater certainty about patent validity would benefit innovators, technological followers, and consumers alike.

Second, differences among national patent systems continue to result in avoidable costs and delays. In spite of progress in harmonizing the U.S., European, and Japanese patent examination systems, important differences in standards and procedures remain, ensuring search

and examination redundancy that imposes high costs on users and hampers market integration. It is estimated to cost as much \$750,000 to \$1 million to obtain comprehensive worldwide patent protection for an important invention, and that figure is increasing at a rate of 10 percent a year. Important differences include the following: Only the United States gives preference to the “first to invent” rather than the “first to file.” Only the United States requires that a patent application disclose the “best mode” of implementing an invention. U.S. law allows a grace period of one year, during which an applicant can disclose or commercialize an invention before filing for a patent, whereas Japan offers a more limited grace period and Europe provides none.

Third, some U.S. practices seem to be slowing the dissemination of information. In the United States there are many channels of scientific interaction and technical communication, and the patent system contributes more to the flow of information than does the alternative of maintaining technical advances as trade secrets. There are nonetheless features peculiar to the U.S. patent system that inhibit information dissemination. One is the exclusion of a nontrivial number of U.S. patent applications from publication after 18 months, an international norm since 1994. A second U.S. idiosyncrasy is the legal doctrine of willful infringement, which can require an infringer to pay triple damages if it can be demonstrated that the infringer was aware of the violated patent before the violation. Some observers believe that this deters an inventor from looking at the patents of possible competitors, because knowledge of the patent could later make the inventor subject to enhanced damages if there is an infringement case. This undermines one of the principal purposes of the patent system: to make others aware of innovations that could help stimulate further innovation.

Fourth, litigation costs are escalating rapidly and proceedings are protracted. Surveys conducted periodically by the American Intellectual Property Law Association indicate that litigation costs, millions of dollars for each party in a case where the stakes are substantial, are increasing at double digit rates. At the same time the number of lawsuits in District Courts is increasing

Fifth, access to patented technologies is important in research and in the development of cumulative technologies, where one advance builds on one or several previous advances.

Faced with anecdotes and conjectures about restrictions on researchers, particularly in biotechnology, we conducted a modest survey of diverse participants in the field to determine whether patent thickets are emerging or access to foundational discoveries is restricted. We found very few cases although some evidence of increased research costs and delays and much evidence that research scientists are largely unaware of whether they are using patented technology. During our study, the Court of Appeals for the Federal Circuit ruled that university researchers are not shielded by the common law research exception against infringement liability. This combination of circumstances – ignorance of intellectual property on the one hand and full legal liability on the other – represents an exposure that universities are not equipped to eliminate by the kinds of due diligence performed by companies and investors.

Toward a better patent system

The NRC committee supports seven steps to ensure the vitality and improve the functioning of the patent system:

1) Preserve an open-ended, unitary, flexible patent system. The system should remain open to new technologies, and the features that allow somewhat different treatment of different technologies should be preserved without formalizing different standards in statutes that would be exceedingly difficult to draft appropriately and equally difficult to change if found to be inappropriate. Among the tailoring mechanisms that should be exploited is the USPTO's development of examination guidelines for new or newly patented technologies. In developing such guidelines, the office should seek advice from a wide variety of sources and maintain a public record of the submissions. The results should then be part of the record of any appeal to a court, so that they can inform judicial decisions.

This information could be of particular value to the Court of Appeals for the Federal Circuit, which is in most instances the final arbiter of patent law. In order to keep this court well informed about relevant legal and economic scholarship, it should encourage the submission of amicus briefs and arrange for temporary exchanges of members with other courts. Appointments to the Federal Circuit should include people familiar with innovation from a variety of

perspectives, including management, finance, and economic history, as well as nonpatent areas of law that bear on innovation.

2) *Reinvigorate the nonobviousness standard.* The requirement that to qualify for a patent an invention cannot be obvious to a person of ordinary skill in the art should be assiduously observed. In an area such as business methods, where the common general knowledge of practitioners is not fully described in published literature likely to be consulted by patent examiners, another method of determining the state of knowledge needs to be employed. Given that patent applications are examined *ex parte* between the applicant and the examiner, it would be difficult to bring in other expert opinion at that stage. Nevertheless, the open review procedure we will describe next provides a means of obtaining expert participation if a patent is challenged.

Gene sequence patents present a particular problem because of a Federal Circuit ruling making it difficult to apply the obviousness test in this field. This is unwise in its own right and is also inconsistent with patent practice in other countries.

3) *Institute an “Open Review” procedure.* Congress should pass legislation creating a procedure for third parties to challenge patents after their issuance in a proceeding before administrative patent judges of the USPTO. The grounds for a challenge could be any of the statutory standards—novelty, utility, nonobviousness, disclosure, or enablement—or the case law proscription on patenting abstract ideas and natural phenomena. The time, cost, and other characteristics of this proceeding should make it an attractive alternative to litigation to resolve questions of patent validity. For example, federal district courts could more productively focus their attention on patent infringement issues if they were able to refer validity questions to an Open Review proceeding. The result should be much earlier, less expensive, and less protracted resolution of validity issues than we have with litigation and of a greater variety of validity issues than we have with re-examination even if it were used.

4) *Strengthen USPTO resources.* To improve its performance, the USPTO needs additional resources to hire and train additional examiners and implement a robust electronic

processing capability. Further, the USPTO should create a strong multidisciplinary analytical capability to assess management practices and proposed changes, provide an early warning of new technologies being proposed for patenting, and conduct reliable, consistent, reputable quality reviews that address office-wide as well as individual examiner performance. The current USPTO budget is not adequate to accomplish these objectives, let alone to finance an efficient Open Review system.

5) *Modify or remove the subjective elements of litigation.* Among the factors that increase the cost and reduce the predictability of patent infringement litigation are issues unique to U.S. patent jurisprudence that depend on the assessment of a party's state of mind at the time of the alleged infringement or the time of patent application. These include whether someone "willfully" infringed a patent, whether a patent application included the "best mode" for implementing an invention, and whether a patent attorney engaged in "inequitable conduct" by intentionally failing to disclose all prior art when applying for a patent. Investigating these questions requires time-consuming, expensive, and ultimately subjective pretrial discovery. The committee believes that significantly modifying or eliminating these rules would increase the predictability of patent dispute outcomes without substantially affecting the principles that these aspects of the enforcement system were meant to promote.

6) *Harmonize the U.S., European, and Japanese patent examination systems.* The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of applications granted or denied. The committee recommends that the United States should conform to practice elsewhere by adopting the first inventor to file system, dropping the "best mode" requirement, and eliminating the current exception to the rule of publication of an application after 18 months. The committee also recommends that other jurisdictions adopt the U.S. practice of a grace period for filing an application. These objectives should be pursued on a trilateral or even bilateral basis if multilateral negotiations do not progress.

7) *Consider enacting a narrowly drawn exception from infringement liability for some research activities.* Here we do not propose specific legislative language, but we do

suggest some principles for Congress to consider in drafting a narrow research exception that would preserve the intent of the patent system and avoid some disruptions to fundamental research.

In making these recommendations, our committee was mindful that although the patent law is designed to be uniform across all applications, its practical effects vary across technologies, industries, and classes of inventors. There is a tendency in discourse on the patent system to identify problems and solutions to them from the perspective of one field, sector, or class. Although the committee did not attempt to deal with the specifics of every affected field, the diversity of the membership enabled us to consider each of the proposed changes from the perspective of very different sectors. Similarly, we examined very closely the claims made that one class of inventors—usually individuals and very small businesses—would be disadvantaged by some change in the patent system. Some of the committee’s recommendations—universal publication of applications, Open Review, and shifting to a first-inventor-to-file system—have in the past been opposed on those grounds. The committee reviewed very carefully, for example, how small entities currently fare in interference proceedings, examination, and re-examination. We also studied how European opposition proceedings impact small businesses. We concluded they enjoy little protection and in fact are often at a disadvantage in the procedures we propose to change. In short, we believe that our recommendations, on balance, would be as beneficial to small businesses and individual inventors as to the economy as a whole.

We appreciate the opportunity afforded by the community to testify on our conclusions and would be happy to answer any questions.

Statement of
William Parker

Chief Executive Officer
Director of Research
Diffraction, Ltd

“Perspectives on Patents”

Before the
Subcommittee on Intellectual Property
Senate Judiciary Committee

April 25, 2005

Mr. Chairman, Ranking Member Leahy, and members of the Subcommittee, my name is Bill Parker and I am the Chief Executive Officer and Director of Research for Diffraction LTD, a technology and intellectual property based small business. Thank you for inviting me to testify today on the very important topic of patent reform.

In my testimony I hope to present some of the views of individual inventors and other small entities on needed changes to the United States patent system. As evidenced by the substantial numbers of innovations and patents that spring from small businesses around this country, and the jobs these innovations create or maintain, even our rural Vermont operation has a role to play in the United States economy and its highly valued high technologies.

My company, Diffraction LTD is not just small, it is a micro-business. This panel's members are by and large from large entities, so I will try to make this presentation as focused as possible on a few issues of patent reform as they affect individuals and small businesses. My apologies in advance if this testimony takes on a personal perspective, but perhaps this approach will help us to remember that it is (still) people that do the inventing.

Introduction

Like many small technology based businesses, our company was founded by an inventor and patent holder, in our case it was my wife Julie. After earning a graduate degree from MIT, and with little or no business background, she decided to start her own company to further develop and capitalize on her skills, talents, inventions and discoveries. She found it was useful to have a partner in business with some experience finding funding and navigating the complexity of intellectual property protection - that's where I came in. As an inventor from childhood, with some reasonable commercial success, I had collected a considerable range of experiences learning about the things one did, and did not do, to capitalize on one's creativity. We started with nothing but a few good ideas.

In the last 15 years our company, now employing over a dozen innovators and a similarly sized professional support staff, has produced a number of commercially viable developments in holography, optics, microelectronics and nanotechnology. Some of these discoveries and intellectual developments have been issued United States "letters

patent”, still others are in the patenting process. We have recently launched an effort to develop innovations that may help win the war against terrorism, work supported with federal government contracts as well as our own private funds. Some of our homeland defense ideas are now in the patent process and will hopefully gain protection as well.

It is important to note that we believe our intellectual property in the long term will have a greater value than our tangible output will in the short term. Said a different way: the product of our minds probably has more value than the things we can make with our hands. This is a theme you will be hearing frequently in representations that there is a need for better patent quality. If intellectual property is not protected with high quality patents, then its value diminishes or goes away.

When we have done our inventing job well, and the result is a product in demand, we may need to depend on others to take our innovation to the market. Like other inventors that choose the licensing route over manufacturing, we then ask for a royalty payment as a return on our investment in the innovation. A royalty bearing license or other payment method is used to transfer the right an inventor has to monopolize their invention on to another party.

Ranging from a few percent and up, a royalty payment is made during the life of the patent and sometimes longer, with terms and conditions negotiated between the inventor (licensor) and the manufacturer (licensee). The licensee using or selling our patented invention wins because he has gained a protected product or process without the

expensive R&D it took to create it. Society wins because independent innovators can think of new products, processes or methods unfettered by limits part and parcel with the corporate decision process or the demands of quarterly profits reporting. As more large companies outsource innovation to companies expressly built around the speedy generation of new processes and products, consistent protection is to everyone's benefit.

That the United States is moving toward an economy where intellectual property (IP) is a significant element of the GDP is undeniable. That we are doing everything we can as a country to protect our IP is questionable. The future world market will need new rules regarding the ownership of ideas, rules that are fair and balanced. I would like to offer an image to the committee of a day when all the US has to offer the world is IP, a few raw materials and some farm produce. This is a scary scenario if we are not prepared or able to protect our most important assets.

As it has since its inception in all other areas, the United States needs to take the ethical and legal high ground with robust, creative and independent approaches required for a fair and equitable marketplace for ideas. I believe that patent reform efforts now in discussion can produce the necessary changes in a relevant time period.

I would like to direct my remaining remarks toward recognizing a few of the critical elements for the success of small technology based businesses that would be affected by patent reform currently under discussion.

Quality of Patents

The patent process must be flawless for a patent to be above question. And it must be above question to have any real value. Thorough examination is all that is required, but as the art becomes more involved and specialized it is increasingly more difficult to factor out mistakes of omission. Better access to prior art is part of the solution, but more is needed in the examination process to prevent a poor outcome despite a significant amount of time and money being spent.

When an examination for a foreign filing uncovers prior art that neither I nor the USPTO examiner had seen before, it leads to a very uncomfortable feeling of “what else didn’t we know about”. I have personally seen improvements in this area in the last few years, hopefully due to better resources being applied to the problem. Resources that need still more improvements, i.e. more money, as well as some “outside the box thinking” on the problem.

Money not spent by the PTO to ensure quality is often spent instead by the patent holders and their challengers in legal actions – when it’s too late for anyone to gracefully back down. Tremendous amounts of money are spent in challenges when a fraction of that could have often prevented the problem at its source. This leads to the appreciation that for many inventors a patent is seen as nothing more than a “license to litigate.” We need to do everything we can to dispel that appreciation.

If it is true that other countries tend to have better prior art examinations than in the US, then perhaps we can determine why. This may be an effect of timing, as our examination may be concluded prior to the commencement of a foreign one, but it may also be that they know how to do better examinations. This should be investigated and if we can learn some new tricks, then let's do it.

There is a need for skilled examiners in emerging technology areas – keep in mind that experts in their specific art are their customers. From biotechnology to nanotechnology, in software and microelectronics as well as other cutting edge fields, the experts are the ones making the inventions – not the ones determining if they are in fact inventions. It is not easy for an examiner to know enough about an emerging field of science, and in particular a specialty area of scientific or technical endeavor, to see the full breadth of a filing's impact or the value of a particular claim.

Regardless of what it takes, in manpower or money, the patent examination process needs to be up to the task. Entrepreneurs depend on a filed patent to interest investors, and if the invention succeeds to the point of a patent but is in fact easily challenged, both sides have wasted time and money that could have been better spent. Patent filings are routinely used by entrepreneurs to protect themselves from confidants that might just as easily become competitors as customers. Everyone benefits if the product of an examination is beyond question.

A post grant review process undoubtedly could improve the quality of the patents issued. Despite the fact that it is a good idea, how does the owner best deal with the wait time in a commercial sense. A patent in limbo for a year is a scary thing from a commercial perspective, but far better that a patent in limbo for its entire life. It would be great to have a system that erased the worry – will the patent that you are building your business on ever be a sure thing?

First to Invent vs. First to File

You will hear much about why we should move to a First to file approach. It sounds like a good approach in many ways for individual inventors, and for the system in general, but in fact it poses a few big problems for small entities.

Due to the high cost of building prototypes or laboratory work, it takes a small inventor longer to go from idea to reduction to practice, and without a sufficient test of reality a patent filing is more difficult to put through the PTO and more suspect when it is. A one year “grace” period following a provisional patent filing is the best protection afforded a small entity - unless it takes over a year to assemble the required funding and then verify the invention, as it often does.

Perhaps there are ways to optimize the first to file approach that levels the playing field with bigger entities. Different rules are already in play for filing costs, why not extend those benefits in other ways as well. A number of efforts are in place to help small entities short circuit this issue of costs to reduce ideas to practice, such as the Small

Business Innovative Research (SBIR) program, but even then only a small fraction of innovative ideas obtains support toward a reduction to practice.

International Protection for Small Entities

We should always be looking for additional ways to encourage the creativity and capabilities of the country's small inventor entities, reduce their costs in obtaining patents, and give them enough extra protection in the world market to keep them, and us, competitive. When our best ideas are being copied wholesale overseas it does nothing to reinforce the inventor's or the public's belief in and support of the patent system.

An issue I hear frequently from independent inventors is how they can do nothing to stop overseas copying of their inventions. When I ask them how they know they are being infringed, they tell me they see their inventions in big chain stores here in the US. What may be needed is both a better understanding of the rights of an inventor to compel a seller of their invention to cease and a less expensive and more responsive means in the courts to enforce this right.

Need for Injunctive Relief

Not all inventors are opportunists or patent predators. A lot of talk is aimed at protecting big businesses from the actions of a few opportunists that would try to use the system in ways it was not meant to be used. If a court reads a situation such that in its estimation harm is coming to the patent holder by way of an infringement, then injunctive relief should be available to the plaintiff. Some would say that the use of a permanent

injunction is excessive, particularly if the patentee does not intend to manufacture the invention themselves. In some ways this is exactly counter to the purpose of a patent as a means to bring new products or processes into commerce.

There is, however, a need to recognize and protect the value independent inventors and other small entities bring to the commercialization “party”. But how best to accomplish this, when there is such a large range of ways patents can be used – and misused? A patentee’s ability to operate in the commercial sense is in part determined by how well they are able to control their intellectual property – with whom they do a deal and under what terms. If their invention has been infringed, willfully or otherwise, and the infringer is not compelled to cease, then not only has the inventor’s rights been abridged, but so has their earning power. Another deal, with another manufacturer at a higher royalty rate and with a larger commercial value could have been the outcome of a clean, preferably exclusive, licensing relationship. Because an infringer is willing to pay a royalty, it is not an indication that they are willing to respect the rights of the patentee in the broader sense. In these cases commerce in general suffers, and the full potential of the patent is in question.

Conclusion

I speak for many of my small entity colleagues when I thank the Committee for this opportunity to be at the table during this hearing. We only ask for more chances to provide views to Congress on this important topic and for more presence on advisory boards during the patent reform debate.

I personally thank you for the opportunity to appear before you today, Mr. Chairman, and I offer my continuing efforts to find, or invent, ways to make our patent system work for the 21st century and beyond.

Statement Of

**Joel L. Poppen
Deputy General Counsel
Micron Technology, Inc.**

**“Perspectives on Patents”
before the
Subcommittee On Intellectual Property
Committee On The Judiciary
United States Senate**

April 25, 2005

Chairman Hatch, Ranking Member Leahy, and Members of the Subcommittee: My name is Joel Poppen and I am the Deputy General Counsel for Micron Technology, Inc. Thank you for allowing me to testify today on the very important topic of patent reform.

The discussion about patent reform, and indeed most of the testimony that will be presented to this Subcommittee today, focuses on a two general areas – improving the quality of patents issued by the Patent and Trademark Office and redressing problems in patent litigation. While Micron generally supports reforms that will lead to the highest quality of patents possible, my testimony today primarily will focus on patent litigation issues that we believe threaten the viability of innovative manufacturers, and ultimately the patent system itself, if not properly addressed through legislation.

* * * * *

Micron is a significant stakeholder in the patent system and, accordingly, has a keen interest in its improvement. Micron is one of the world's leading providers of advanced semiconductor solutions. Micron's DRAM and Flash memory components are used in today's most advanced computing, networking, and communications products, including computers, workstations, servers, cell phones, wireless devices, digital cameras, and gaming systems. Micron also provides CMOS image sensor solutions to the handset camera, digital still camera, and PC video camera markets. Micron is driven by an unwavering commitment to be the most efficient and innovative global provider of semiconductor solutions.

Micron's investment in research and development, and the company's focus on innovation, has led to a portfolio of over 12,000 U.S. patents. For the past five years, Micron has been among the top ten recipients of U.S. patents. In 2004, Micron was awarded 1761 U.S. patents. For the last three years, MIT's *Technology Review* has ranked Micron's portfolio as number one in technological strength among the semiconductor industry.

I. INTRODUCTION

Without question, a strong patent system is essential to today's technology-based economy. By granting a period of market exclusivity to patent holders, the U.S. patent system has historically encouraged investment in new and innovative products and services. This system has performed admirably as a powerful engine of technological growth. In recent years, however, increasing numbers of opportunists have exploited weakness or loopholes in the patent system to effectively achieve a "hold up" of those who innovate, manufacture, and bring products to consumer markets. Such abuse threatens to undermine the intended incentives of the patent system and to harm real innovation.

The legal environment has become more favorable to patent opportunists at the expense of innovators. This trend is responsible, in substantial part, for the 60% increase in the annual number of patent suits filed in district court over the last ten years. In addition, the typical costs of defending a patent litigation are at least \$3 million, and often multiple times that amount.¹ As experts pointed out in a recent book analyzing the breakdown of the patent system, "[g]iven these large costs [of defending a patent infringement suit], and the realization that cases seem to have increasingly favored patent holders, even targets that think they are not infringing have a strong economic incentive to give in rather than fight. This means there are probably many cases of stifled competition."² This "burgeoning patent litigation is increasingly making lawyers the key players in competitive struggles rather than entrepreneurs and researchers. As the patent system becomes a distraction from innovation rather than a source of incentive, the engine of technological progress and economic growth begins to labor."³ To curb the growing abuse and to realign the intended incentives, the patent system must be reformed through targeted legislation.

II. PATENT SYSTEM ABUSES AND LEGISLATIVE SOLUTIONS

The most significant problems with the patent system, and those that demand the most immediate attention, can be corralled into three categories: "inventing patents" rather than patenting inventions; improper litigation leverage; and excessive and disproportionate damages awards. I will address each of these categories by describing the abuse, explaining the real-world implications, and proposing the appropriate legislative remedy.

A. "Inventing Patents" Rather Than Patenting Inventions

One area of patent system abuse relates to an increasing number of manufacturers, both large and small, coming under attack from those who are "inventing patents" rather than patenting inventions. These "inventors of patents" use a variety of techniques, including "patent stalking" (also sometimes referred to as "submarine patenting"). In general terms, patent stalking refers to the process of tailoring patent claims over time to cover the legitimate activities

¹ American Intellectual Property Law Association, *Report of Economic Survey 2001*, Arlington, VA (2001) (survey of 248 patent litigators found a median estimate of \$3 million in costs of defending patent litigation with more than \$25 million at stake).

² *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Adam B. Jaffe and Josh Lerner, Princeton University Press (2004) at 68.

³ See *id.* at 13.

of others. The “patent stalker” first files a broad patent application describing the expected future direction of an industry in very general terms. Then, while maintaining the application in secrecy, the stalker monitors innovative manufacturers and watches how technologies are ultimately developed and implemented. Often, they monitor industry standards-setting organizations to learn future technology direction. With this information, the so-called “inventor” can amend the pending claims over time (typically utilizing multiple “continuation” applications and taking advantage of the original filing date of the original application) to cover the activities of a given industry.

In most cases, the “patent stalker” waits until manufacturers are locked in to the particular technology before surprising them with unanticipated patent claims (and often steep) royalty demands. The targets of these assertions are unaware of the claims because the patent and claims may not become publicly available until the patent issues. Although the American Inventors Protection Act of 1999 mandates publication of applications at eighteen months after filing, that provision carves out a broad exception for inventors to opt out of the requirement if the inventor elects not to pursue foreign patent rights. Putting aside the problem of secrecy, even if the application and pending claims were published at eighteen months, nothing currently prohibits the inventor from pursuing different, even broader, claims during an extended prosecution period (provided those claims are supported by the specification of the patent) that will eventually cover technology adopted by the industry.

In an increasingly common model for attacks on manufacturers, individuals intent on patent profiteering form a company solely to develop or acquire patents and exploit them for financial gain rather than to bring new products to market. Engineers flock from research and development at manufacturing companies to these professional patent firms. In return for “inventing patents,” these engineers share in the cash flow generated by the exploitation of the patents against others. In a variant of that model, lawyers or professional patent firms purchase patents to assert against manufacturers. Many patents owned by distressed or bankrupt companies can be acquired at minimal cost or for a share of the potential bounty gained from the exploitation of the patents.

Regardless of the type or label, “inventors of patents” have at least one thing in common: they do not use patents to protect their own products or market their own technology (which is the underlying justification for every Patent Act since the original Patent Act of 1790). Instead, they use patents to extract unfair royalties from industry innovators who bring the benefits of innovation to the public by actually engaging in the manufacture and sale of products in those markets. Of course, the patent system was never intended to encourage or protect these sorts of activities. The purpose of the patent system is well known – it provides incentives to would-be innovators to invest the resources necessary to bring the benefits of inventions to the public.

But, contrary to the underlying bargain of the patent system, “patent inventors” do not teach, sell, or transfer any technology or know-how at all. Instead, they “manufacture” patent claims and then “sell” a royalty bearing license allowing the victim to avoid an infringement lawsuit and the threat of a fatal injunction. Ultimately, the unfortunate targets of tailored patents who refuse to meet these royalty demands face an expensive patent infringement lawsuit and the grave threat of an injunction shutting down their business if they fight the patents and lose. The

predicament is further exacerbated when the patents are asserted by professional patent firms who do not manufacture anything and accordingly are not at risk of a counterclaim based on the target's patents. The result is an increasing and substantial "royalty tax" on U.S. industry – including the most innovative companies in the nation – without any of the benefits otherwise guaranteed by the patent system.

The patent laws need to be amended to redress the "inventing patents" abuse. First, applicants should be required to file the broadest claims to which they believe their invention entitles them within twelve months of filing the original application. No claim broadening should be permitted beyond the twelve month deadline, whether presented in the same application, as part of a continuation application, or as part of a reissue application. Inventors should disclose to the public the full scope of what they think they invented and should not be allowed to abuse the system by later claiming a broader or different invention after watching the evolution of technology and products. Twelve months is an objectively reasonable period of time for inventors to identify the maximum scope of patent protection sought.

To implement the change, 35 U.S.C. should be amended by creating a new section 123. Section 123(a) would codify the requirement of submitting the inventor's broadest claims within twelve months. Section 123(b) would help ensure that applicants will not submit overtly broad claims to try to circumvent the intention of section 123(a). The specific proposal is to add the following language:

35 U.S.C. § 123

(a) No enlargement of the scope of the claims submitted within 12 months of the earliest date for which a benefit is sought under this title shall be permitted in the prosecution of an application, or in any application which claims the benefit of the filing date of such application.

(b) A patent shall be unenforceable if it issues from, or claims the benefit of the filing date of, any application that contained a claim that was known at the time of submission to be unpatentable under any of the conditions set forth in section 102 of this title by persons then having a duty of candor and good faith with respect to such application.

An additional amendment is needed to 35 U.S.C. § 251, Reissue of defective patents, to prohibit broadening claims in the patent reissue process. The last clause of the last paragraph of section 251 should be struck as follows:

~~"No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent."~~

Second, the publication requirement should be amended to eliminate the opt out exception for inventors who forego foreign patent rights and to require publication of the claims filed by the twelve month period prescribed above. Publication of pending applications permits

manufacturers to research the patent landscape so as to make informed decisions regarding whether to invest resources in a certain technology, design around that technology, or approach the patent applicant for a license on reasonable terms before committing significant capital and resources. Requiring the publication of the inventor's broadest claims permits a manufacturer to examine them and learn the maximum potential scope of the claims of any patent that might issue from that application. Permitting an exception to the publication requirement or avoiding the publication of broadest claims not only thwarts the important analysis described above but also provides "inventors of patents" a cloak under which to secretly tailor patent claims.

35 U.S.C. § 122 governs the confidential status of applications and the publication of patent applications. To require that the claims be published with the application, 35 U.S.C. § 122(b)(1)(B) should be amended as follows (additions in italics):

(B) No information concerning published patent applications shall be made available to the public except as the Director determines; *provided, however, that at least all claims submitted within 12 months from the earliest filing date for which a benefit is sought under this title shall be published either with the application, or separately therefrom if the application was published earlier at the request of the applicant pursuant to subparagraph 1(A).*

Section 122 should be further amended by striking subparagraph 122(b)(2)(B) in its entirety to eliminate the opt out exception from the publication requirement for applicants who chose to not pursue foreign patent rights.

B. Improper Litigation Leverage

Another area of abuse relates to the ability of patent plaintiffs to, in effect, extort payments from manufacturing targets by leveraging significant judge-made advantages in the patent litigation process. When plaintiffs prevail at trial, the trial court virtually automatically enters an immediate injunction shutting down a defendant's business even though the applicable statute clearly requires that "principles of equity" be weighed. Moreover, plaintiffs enjoy a presumption that a patent is valid that can only be overcome by defendants proving that the patent is invalid by "clear and convincing evidence" – a very tall burden created by the courts. In the face of this significant litigation leverage and given the company business at stake, defendants often are compelled to enter into an expensive license rather than challenge the patent.

As noted above, the patent system encourages investment in research, development, and infrastructure that brings the benefits of innovation to the public. As long as an inventor's ability to obtain a just reward is secure, the incentive to innovate intended by the patent system is preserved. Where the patent holder manufactures products under the patent, the reward typically takes the form of an ability to sell the product to the exclusion of other manufacturers. If the patent is infringed, the manufacturing patentee can recover lost profits or other damages. Where the patent holder does not manufacture or sell a patented product, then the award typically takes the form of money exchanged for the patented technology since there is no benefit to the patent holder of excluding the manufacturer.

Current law draws no distinction between these two types of patent plaintiffs and offers, without analysis, the same remedies to both. When a patent plaintiff prevails, courts must consider whether to permanently enjoin the defendant from practicing the infringing activity. Injunctions may be granted only “in accordance with the principles of equity.” Historically, courts addressing the issue of injunctions in many different civil contexts have satisfied this requirement by performing an “equitable balancing test” to assess the level of harm that would come to the plaintiff if an injunction did not issue and to weigh that against the harm the defendant would suffer if an injunction did issue. In patent infringement cases, as in other injunction situations, courts must find a patent owner’s harm to be “irreparable” before an injunction is appropriate. In recent years, courts in patent cases simply have shortcut the analysis and virtually automatically granted injunctive relief by presuming that the patentee will suffer irreparable harm if an injunction does not issue.

However, there is simply no basis for courts to ignore a balance-of-harm analysis. Automatic entry of a permanent injunction against an infringer is not necessary to implement the Constitutional and statutory purpose of the patent system. That purpose is satisfied as long as the patentee receives fair compensation for infringement. The patent laws should ensure that patent owners, particularly those that do not practice their own inventions, are not automatically entitled to an injunction against manufacturers. Those who use patents merely to collect royalties should be entitled only to collect monetary damages from infringers and not to shut down companies who have taken the entrepreneurial risk of developing, manufacturing, and selling innovative products.

Patent owners also profit from an unjust advantage over manufacturing targets because of the significant hurdle defendants face in invalidating patents. Patents issued by the Patent and Trademark Office are presumed valid. To overcome that presumption, defendants must prove that the patent is invalid by “clear and convincing evidence.” That high standard clearly is unjustified given the way in which applications are evaluated and patents are issued. Inventors convince an examiner in the Patent and Trademark Office of the patentability of the invention without any input from outside parties. A number of factors dictate that a strong presumption of a patent’s validity is inappropriate: the Patent and Trademark office is underfunded; patent examiners have limited time to evaluate applications and must search for prior art themselves; a claimed invention is presumed to be patentable unless the examiner can prove otherwise; and, the Patent and Trademark Office allows patents based on a “preponderance of evidence” standard.

The presumption of validity of a patent and invalidity defenses are described in section 282 of the Patent Statute. Nothing in section 282 mandates “clear and convincing evidence” to overcome the presumption of validity. Section 282 was originally intended as a mere “burden shifting” device requiring the challenger to first come forward with evidence of invalidity. Then, the burden shifts to the patent owner to rebut the showing by the challenger. Given the presumption, ultimately the challenger must persuade the court that the patent is invalid in light of all the evidence. Importantly, the “clear and convincing evidence” standard is a creation of the courts. Given the circumstances under which patents issue, a “preponderance of evidence” is

the appropriate standard. That standard will permit targets to challenge questionable patents and will help take away inappropriate leverage from patent opportunists.

The patent laws need to be amended to redress the “litigation leverage” abuses. First, the injunction statute, 35 U.S.C. § 283, should be amended to eliminate the presumption of irreparable harm and to preclude the entry of an injunctive remedy at the conclusion of a patent case unless the court finds that it is appropriate after considering all the equities. Courts must consider the relative harm to each of the patentee and the infringer and must weigh all of the evidence tending to establish or negate the equitable factors traditionally considered relevant to irreparable harm. Accordingly, 35 U.S.C. § 283 should be amended as follows (additions in italics):

35 U.S.C. § 283 Injunction

(a) The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms and conditions as the court deems reasonable.

(b) A court shall not grant an injunction under this section unless it finds that the patentee is likely to suffer irreparable harm that cannot be remedied by payment of money damages. In making or rejecting such a finding, the court shall not presume the existence of irreparable harm, but rather the court shall consider and weigh evidence, if any, tending to establish or negate any equitable factor relevant to a determination of the existence of irreparable harm.

Second, 35 U.S.C. § 282 should be amended to codify the appropriate standard for establishing the invalidity of a patent as “preponderance of the evidence.” The last sentence of the first paragraph of section 282 should be amended as follows (additions in italics):

35 U.S.C. § 282 Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. *Such burden may be satisfied by a preponderance of the evidence.*

C. Excessive and Disproportionate Damage Awards

A final area of patent system abuse relates to excessive and disproportionate damage awards to plaintiffs in connection with a finding of patent infringement. Damages are often vastly disproportional to the actual contribution of the supposed invention because damages are awarded based on the entire value of the product sold – even when the invention actually claimed in the patent is merely a small component of a larger, unpatented system. Additionally, if the infringement is determined to be “willful,” the court may increase the damage award by as much as three times. Unfortunately, a court may punish a defendant with such treble damages even where there is no evidence that the company intentionally copied the patented invention or engaged in any sort of egregious or reprehensible conduct.

Not surprisingly, patent opportunists have pursued every means available to maximize damage claims. A common strategy employed by patent plaintiffs is to make broad and sweeping accusations of infringement against a defendant. To increase the threat, patent opportunists stretch their legal theories of patent infringement beyond what was intended in the law, including alleging that entire products or processes infringe a patent that is focused only on a small, and often insignificant, part of a larger product or process. The opportunist’s goal is to generate a giant damages base and to place as great a proportion of the defendant’s business and manufacturing operations under threat of injunction as possible.

Courts have struggled to find the appropriate measure for damages. In 1970, for example, one court articulated fifteen factors that should be considered in assessing the appropriate measure of damages.⁴ Some of these “Georgia-Pacific” factors weigh heavier than others and not all factors apply to every case. One important factor, however, requires the court to consider “the portion of the realizable profit that should be credited to the invention as distinguished from any non-patented elements, manufacturing process, business risks or significant features or improvements added by the infringer.”⁵

In response, inventors have learned to abuse the patent system and increase leverage against manufacturers by pursuing “system claims” in the Patent and Trademark Office. These clever claims insert the crux of the predator’s “innovation” into much larger contexts than that to which the inventor is rightfully entitled. For example, the abuser may actually have invented a hinge mechanism, but draws the patent claim to a door including the hinge mechanism. In this example, the door is well known to, and long in use by, the public, but in the subsequent litigation, the patent predator claims entitlement to, and the court awards, damages based on the entire value of the door rather than on the value of the innovative hinge.⁶ Faced with these broad patent claims issued by the Patent and Trademark Office, courts have defaulted to a damages base that includes the value of the entire structure or process containing numerous features even though only one of those features is the patented invention (sometimes referred to as the “entire market value rule”).

⁴ *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp 1116 (S.D.N.Y. 1970).

⁵ *Id.* at 1120.

⁶ *Slimfold Mfg., Inc. v. Kinkead, Indus.*, 932 F.2d 1453 (Fed. Cir. 1991).

On top of disproportionate damages claims, defendants typically are faced with allegations of “willful” infringement and the threat of triple damages. In the early 1980’s, the Court of Appeals for the Federal Circuit created a “duty of due care” for manufacturers who are accused of infringement to obtain an opinion of independent counsel.⁷ Under that duty, manufacturers accused of infringement must investigate the scope of the patent and form a good-faith belief that it was invalid or that it was not infringed.⁸ That obligation led to the application of a harmful adverse inference in litigation if the accused manufacturer either failed to obtain an opinion, or, in cases where an opinion was obtained, elected not to rely on the opinion as a defense to an accusation of willful infringement (a defense that requires the defendant to waive the attorney-client privilege with respect to any advice contained in the opinion).

Many manufacturers are routinely bombarded with letters alleging infringement (sometimes referred to as “notice letters”). The companies must make the difficult choice of whether to retain patent lawyers to provide an opinion of counsel for such notice letters. Often the infringement claim is weak or the validity of the patent is dubious at best, and each opinion is expensive. On the other hand, if companies choose to forego obtaining an opinion for any of a number of reasons, they face the daunting prospect of a willful infringement finding at trial (even in a closely contested case).

Because of the inequities associated with the adverse inference and outcries by patent targets, the Court of Appeals for the Federal Circuit recently reconsidered the issue.⁹ Although the court did away with adverse inferences, it did not do away with the duty of due care. Accordingly, substantial confusion remains on the extent to which the obligation to obtain an opinion of counsel remains. The failure of the infringer to have consulted with counsel likely will still be called to the jury’s attention, and the jury may still decide that the defendant’s actions in disregard of the patent owners rights should be punished. To eliminate the need for such wasteful, inefficient, and expensive practices, legislative reform is needed to remove the court-created “duty of due care.”

Some patent reform proposals have suggested that a finding of willful infringement should be condition upon the infringer receiving notice sufficient to trigger declaratory judgment jurisdiction and failing to get an opinion of counsel. However, that solution is problematic because the threshold for declaratory judgment jurisdiction is a moving target, and because patent owners ultimately will simply craft a letter that meets the requirements. Instead, the issue of willful infringement should focus on the infringer’s conduct, and not on the skill the patent holder uses to put the infringer on notice.

Willful infringement is merely a predicate act to the enhancement of damages (under 35 U.S.C. § 284) and enhanced damages are punitive in nature.¹⁰ As in other contexts, to justify a punitive remedy, conduct must rise to the level of “egregious or reprehensible.” Accordingly, the damages statute should be amended to focus on whether the defendants conduct at the time it

⁷ *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90 (Fed. Cir. 1983) (affirmative duty “to seek and obtain competent legal advice from counsel” for alleged infringing activities).

⁸ Courts have also imposed that duty on companies who merely are aware of the existence of another’s patent, even before the patent holder alleges the company infringes the patent.

⁹ *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F3d 1337 (Fed. Cir. 2004).

¹⁰ *Id.* at 1348 (Judge Dyk’s dissent).

initiated the infringing activity was “egregious or reprehensible.” Defendants who are put on notice may still choose to rely on an opinion of counsel, and the court will consider that as part of the totality of circumstances of the behavior, but an opinion of counsel no longer should be required to avoid a finding of willful infringement.

The patent laws need to be amended to redress the “excessive damages” abuse. First, damages should be limited to the proportion to the value directly attributable to the invention rather than the larger system or process in which the patented contribution resides. 35 U.S.C. §284 should be amended by adding the following to the end of the first paragraph (additions in italics):

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court. *Whenever the invention is incorporated into, or is made part of, a method or apparatus otherwise known in the art or attributable to others, or is an improved method or apparatus including within it elements otherwise known in the art, then any award of a reasonable royalty or other damages shall be based only upon such portion of the total value of the method or apparatus as is attributable to said invention alone and shall not include value attributable to the method, apparatus or elements otherwise known in the art or attributable to others.*

Second, willful infringement should be addressed so that enhanced damages are possible only upon an express finding of egregious or reprehensible conduct. 35 U.S.C. §284 should be amended by adding the following to the end of the second paragraph (additions in italics):

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. *Increased damages under this paragraph are punitive in nature and may be awarded only upon a finding of egregious or reprehensible conduct. In considering the existence or absence of egregious or reprehensible conduct, the infringer’s failure to exercise due care to avoid infringement shall not be considered. Only the infringer’s knowledge and conduct as of the time it initiated its infringing activity shall be relevant.* Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The presentation of evidence in support of a finding of egregious or reprehensible conduct shall be to the court, rather than to the jury, and only after a finding of liability has been entered against the infringer.

The court may receive expert testimony as an aid to the determination of damages or on what royalty would be reasonable under the circumstances.

III. CONCLUSION

The growing abuses of the patent system have led to a unique form of litigation abuse that facilitates preying on the very implementers of technology upon which the economy relies. The relative “strength” of the patents that are the subject of these suits, or the relative contribution to the public store of knowledge, rarely plays itself out in court as few innovators can afford to risk years of research expenditures and significant investments in plant and equipment in protracted patent litigation.

Targeted manufacturers face a Hobson’s choice – daunting litigation costs, evidentiary standards slanted toward patent owners, exorbitant damage awards, and virtually certain injunctive relief, on the one hand, and predatory licensing demands on the other. As a result, the innovative manufacturer is forced to avoid or settle even unmeritorious patent lawsuits by paying high licensing fees. The resulting displacement of otherwise productive research and development investments from manufacturing companies to patent predators increases overall consumer costs, delays the introduction of new technologies to the market place, lessens competition, and ultimately puts U.S. manufacturing jobs at risk. Patent reform legislation is essential to curb abuses, alleviate the hold-up of innovative manufactures, and protect the integrity of the patent system.

Testimony of

David Simon
Chief Patent Counsel
Intel Corporation

For the
Business Software Alliance (BSA)
“Patent Quality and Improvement”

Before
Subcommittee on Internet and Intellectual Property
Senate Judiciary Committee
April 25, 2005

Mr. Chairman and members of the Subcommittee, my name is David Simon and I am Chief Patent Counsel for Intel Corporation. I appear today representing the Business Software Alliance (BSA)¹, which welcomes the opportunity to appear before you on this important topic. We commend you for holding these hearings and for your commitment to improving our patent system.

The incentives provided by the patent law are indispensable to the current and future strength of the technology industry. Patents play an essential role in how software and computer companies do research and how they develop products and services. More fundamentally, patents are at the core of our economy’s ability to successfully innovate, and have been since 1789.

¹ BSA members include Adobe, Apple, Autodesk, Avid, Bentley Systems, Borland, Cadence Design Systems, Cisco Systems, CNC Software/Mastercam, Dell, Entrust, HP, IBM, Intel, Internet Security Systems, Macromedia, McAfee, Microsoft, PTC, RSA Security, SAP, SolidWorks, Sybase, Symantec, UGS and VERITAS Software.

Given the importance of patents, we believe that periodic updating of the law is not only a good idea, but also essential to ensuring that patents remain an indispensable contributor to technological progress.

Let me state at the outset that the patent law is not broken. The law is fundamentally sound and works well. Professors Lerner and Jaffe in their recent book characterized the patent system as sand in the gears rather than fuel in the tank of innovation. BSA disagrees with this assessment. I would like to point out that, with one exception, all of the U.S.-based top ten issuers of U.S. patents are members of our organization. The one exception -- Micron Technology -- is also here today as a witness. Thus, as the largest US based customers of the Patent & Trademark Office, we have strong, first-hand knowledge of a system that continues to yield substantial incentives. As with all good things, however, we believe that critical improvements are needed to make the law work better in light of new developments in the marketplace and technological progress, including its application by the courts, and the patent examination process.

We approach patent reform from a pragmatic, problem-solving perspective. While any number of improvements can be made in the law, our attention is focused on those areas of the law and practice that present specific challenges for our companies' day-to-day businesses. In my testimony today, I would like to focus on three matters: 1) why patents are important to technology companies; 2) some of the problems our industry has identified within the current patent regime; and 3) certain areas where we feel improvements are timely.

Patents are Important to Technology and Innovation

The software and computer industry is among the most dynamic forces in the economy today; a creative engine that powers innovation and growth. The industry's products and services give individuals and organizations the tools they need to operate intelligently, efficiently and productively.

As we enter the 21st Century, the principle embraced by our forefathers in Article 1, Section 8 of the Constitution remains sound and perhaps takes on even greater importance than in previous times. Intellectual property is a source of economic value to society, individuals, companies and governments alike.

While copyrights have been and will remain a principal way that technology companies protect their intellectual property, I will limit my comments today to patents.

The increased importance of patents to technology companies has resulted from a mix of legal and marketplace developments. The 1981 Supreme Court decision, *Diamond v. Diehr*, signaled a turning point in the patentability of computer-implemented inventions. In that case, the Supreme Court held that a process that transforms materials physically under the control of a computer program was patentable. The Court's decision clarified earlier rulings that had been interpreted to suggest that software programs would rarely qualify for patentability. Subsequent decisions from lower courts have further clarified the law in this area. As a result, U.S. patent applications from inventors in the software sector have been increasing steadily.

An equally important factor is the impact of marketplace trends. In today's diverse technology marketplace, heterogeneity has become an important element of technology and network effectiveness. Unlike the early days of computing, when consumers tended to purchase their hardware and software from a single firm, consumers now often piece together systems based on products sourced from different suppliers. The ability of these different systems to work together is essential. Patents enable computer and software companies to share technologies, integrate systems and meet consumer's needs, while ensuring a return for these companies' inventions.

Today, patents are a key part of virtually every software and computer company's intellectual property strategy. The reasons are simple.

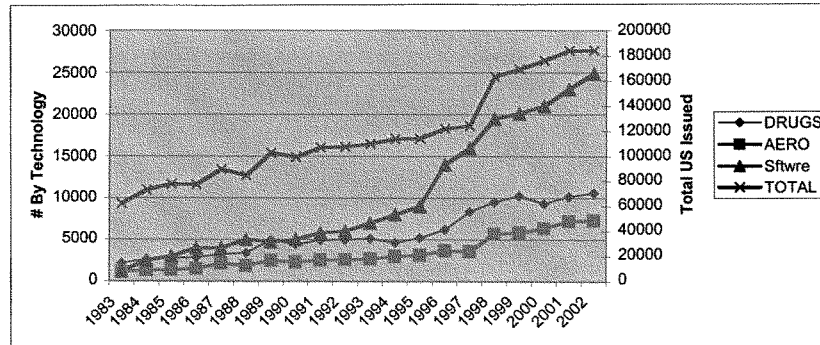
- Patents ensure that software and computer companies have the opportunity to be compensated for their contributions to advances in their field of technology.

- At the same time, and reflecting the way in which our industry operates, patent protection enables software developers to license or otherwise share key technologies with customers, partners and even competitors, while still allowing those developers to prevent third parties from “free-riding” on their innovation.
- Patent portfolios can also serve other important business-related objectives, such as encouraging dissemination of technology through cross-licensing, with a proper balance restored to issues such as willfulness.

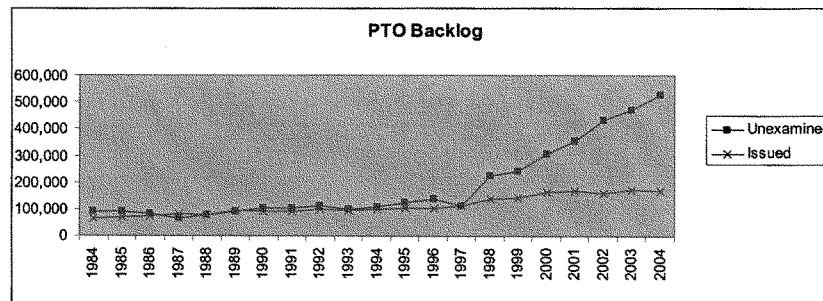
Improvements Are Timely

There are certain aspects of the patent law that present challenges for the software and computer industry. Prior art (the database of previously issued patents and previously known technologies against which a new invention is measured to ensure it merits a patent) is not as well developed for software as it is in some other areas. In part this is because for many years, patents were not readily available for software, and the database is thus still evolving. This makes the task of the examiner difficult, and the result can be poor quality patents. Computers and computer programs are complex technologies, consisting of hundreds of parts and often millions of lines of code. Thus, it is not always easy to determine whether a specific patent application meets the standards of patentability. Because potentially hundreds of patents may be relevant to a particular computer or software technology, it is often very hard to determine whether infringement may be an issue. Finally, because computers and software are composed of many elements which all have to work together, it has been the practice of the industry to cross-license patents, as is the case with other similarly situated industries (for example, the automotive industry).

This problem is greatly exacerbated by the very large number of patents in the software and computer industry. Software and semiconductor patents have been issued in recent years at a rate between three and five times as fast as patents issued in other industries, for example pharmaceuticals and biotechnology. At the same time, the backlog of unexamined patents by the PTO has increased substantially.



Source: Patent and Trademark Office data.



Source: Patent and Trademark Office data.

We approach patent reform from this context -- very rapidly expanding universe of relevant patents and the continuing explosion of patent applications -- and we believe that patent reform legislation should have two primary objectives:

1. To improve the quality of issued patents.
2. To minimize disruptions caused by litigation, specifically, cases brought by persons in search of a quick buck through settlement negotiations, rather than by a party legitimately asserting a right.

Patent Quality

Poor quality patents, as detailed in recent studies by the National Academy of Sciences and the Federal Trade Commission, hamper competition and harm innovation. A questionable patent may lead competitors to forego research and development in a particular area, fearful of the risks that may be involved. Poor quality patents may also require innovators to unnecessarily license thousands of patents.

To ensure patent quality, policymakers should focus on three key areas:

Adequate Training and Funding.

A key concern expressed by many users of the patent system is the lack of patent office resources. We share this concern. When patent offices are adequately staffed and funded, patents are more likely to be awarded promptly and the overall quality of awarded patents is likely to be high—though, to be clear, we believe that quality is far more important than speed. By contrast, when patent offices suffer from inadequate staffing or other resource constraints, patents are both more likely to be delayed or even denied to deserving inventions, and more likely to be granted to inventions that do not, in fact, qualify for protection. Questionable patents, in turn, create uncertainty for software companies and computer companies who must work around the possibility that the patent may be asserted.

BSA encourages Congress to ensure that the U.S. Patent and Trademark Office has the resources it needs to conduct patent examinations that are efficient, expedient and of the highest quality. Enactment by the 108th Congress of legislation to provide modest and necessary increases in PTO fees has enabled the agency to begin to provide additional staff and training in certain software-related technology disciplines. These efforts would be greatly complemented by permanently ending the practice of diverting patent application fees to the general treasury. Allowing the Patent and Trademark Office to retain the fees that it generates would help ensure that the Office is able to provide high-quality examinations and to fund further improvements. We also applaud the PTO's strategic plan, which will also lead to improvements.

Post-Grant Opposition

The primary way to challenge a patent under current law is through litigation, a costly and difficult approach. In order to avoid litigation in those cases where it is not truly necessary, Congress should create a meaningful and balanced post-grant opposition procedure enabling third parties to challenge issued patents. Establishing an administrative procedure for post-grant review and opposition would permit important challenges to patent validity, short of litigation. Under such a system, the person opposing the patent should be required to make a suitable threshold showing. An administrative patent judge should preside over the proceedings, permitting cross-examination and carefully circumscribed discovery, and have appropriate sanction authority. Limitations must be included to protect against abuses of this provision, such as undue delay and harassment. The timeframe for initiating an opposition is critical and should be sufficiently long to provide for meaningful assessment of the granted patent; we recommend two years from grant or one year from receiving notice of patent infringement, to enable a person considering filing an opposition to assess the impact and merit of the patent at issue. Furthermore, given the unique circumstance that hundreds or thousands of patents may apply to each of our products, having a second window to address patents of poor quality that may be asserted is necessary in order to make the post-grant review process meaningful.

By way of example, our industry frequently adopts standards that have to pick between various different techniques to permit interoperability or exchange of information. At that point, a patent that previously was unimportant can become critical to an entire industry when a patentee tries to take advantage of the uncertainties on claim interpretation and interprets its patent for the first time to cover that standard. This could be years after such an obscure patent has issued. Thus, it is important that the period for oppositions in our industry last much longer than the 9 months many others have suggested.

Prior Art

Steps should be taken to enhance patent examiners' access to relevant prior art in the examination process. Under current law, a listing of references in the patent file history creates a presumption that the references were considered by the examiner, even in cases where it is apparent that such references were not fully considered. Furthermore, in existing law, an issued patent is presumed valid and any party challenging validity must overcome its burden by "clear and convincing evidence." As a consequence, although current law does not bar a party from bringing prior art to the attention of the examiner, the presumption that referenced prior art was considered by the examiner, coupled with the high burden necessary to overcome the presumption, severely discourages parties from doing so.

To address this imbalance, we recommend changes to the effect that information and references deemed to be considered during examination shall be only those where the Director explicitly indicates the scope and relevance to the examination of such information and references. Moreover, we believe that the evidentiary rule should be "preponderance of the evidence" for challenging the validity of a patent based in whole or in part on information or references not considered during examination.

Submissions By Public Of Prior Art With Commentary

Under current law, members of the public with relevant prior art information are not free to submit that information to the examiner. The result is that patents are often granted on the basis of incomplete prior art information. To address this issue, we believe Congress should establish a mechanism for the public to submit prior art and other information relevant to patentability. We believe this would increase the likelihood that examiners become aware of most relevant prior art. To prevent the PTO from being buried in a barrage of irrelevant prior art references, persons making such submissions should be required to (1) include an indication of the teaching and applicability of each reference submitted to the patent application at issue, and (2) include a sworn declaration attesting to the relevance and accuracy of the submissions.

Patent Harmonization

BSA member companies derive a substantial portion of their revenues overseas and hold numerous patents in all major jurisdictions. We support efforts to harmonize U.S. laws with those of other major countries.

While we favor harmonization, we are concerned about dramatic changes suggested by some other organizations. First, the U.S. Government is involved in negotiations on patent harmonization and we believe that it would be ill advised for premature action to handcuff the government's negotiating flexibility. Second, the proposals that we have seen go far beyond harmonization and, instead, eliminate longstanding statutory bars, such as the on sale bar and public use bar in current section 102(b). Third, the proposed amendment would limit the public knowledge to a new test where the knowledge is "reasonably effectively accessible," while interjecting into prior art analysis the written description requirements. Given that much of the public knowledge in our industry is often demonstrated by reference to parts of software with millions of components, this would lead to a dramatic scaling back of the scope of prior art in the software and computing industries.

Abuses of Continuation Practice

Currently, a patent applicant may continue to amend its claims after publication of its patent application. Through these mechanisms, some applicants keep their applications pending for extended periods, while monitoring the developments in the relevant market, and then modifying their claims to cover competitors' products after those competitors have invested significant funds in their products, often in a good faith attempt to avoid infringement. To address this problem, patents should not be issued on any claim that is broader than the broadest claim previously published or issued.

Disincentives to Domestic R&D

In 1984, the Congress added Section 271 (f) to the patent law to prevent companies from manufacturing parts for an infringing product in the U.S, and exporting those parts for assembly abroad to avoid the claim of infringement. Today, that provision has been

interpreted by the courts in ways that deter domestic development of software. Under recent court holdings, copies of a computer program made outside the United States are nonetheless calculated as part of assessing damages if the copies are made from a master disk developed and exported from the U.S. If the software had been developed outside the U.S., this rule would not apply. We believe this provision creates an unintended incentive to move software development outside the U.S., and should be deleted.

Inter Partes Reexamination

Under current law, the reexamination process is so restricted as to severely limit its applicability. We believe that a change in the law is needed to the *inter partes* reexamination procedure to allow a third party a limited, but more effective opportunity to request that an issued patent be reexamined. Such a change should increase the utility of the reexamination process by relaxing its estoppel provisions and expanding its scope.

Reduce the Disruptions Caused by Litigation

Today, approximately 300 patent infringement cases are pending against hardware and software companies, and these companies pay about \$500 million each year defending themselves in these cases. Too many of these cases are filed in search of a quick buck through settlement negotiations, rather than by a party legitimately asserting a right because the infringer is interfering with commercial objectives. This is not to say that all of these cases are without merit, but too many are.

Three aspects of current law and jurisprudence require Congressional attention.

First, the way the courts have assessed damages poses serious disruptions. Under today's law, punitive triple damages are imposed if the party infringed willfully. Mere knowledge that the infringed patent exists can support a finding of "willfulness," and liability for triple damages. Contrary to what would appear to be controlling Supreme Court precedent, no requirement of bad faith or egregious conduct is required for the imposition of what are properly viewed as punitive rather than compensatory damages. This creates two serious problems. Because mere knowledge of a patent can create this

liability, some have indicated that they do not read their competitors patents out of concern for such potential treble damage liability. The FTC concluded that, among other things, failure to read competitors' patents can jeopardize plans for a non-infringing business or research and encourage wasteful duplication of effort. Second, once a party is put on notice that it may be infringing, the usual practice is to seek an opinion letter from counsel. This has turned into a cottage industry for lawyers, at the expense of patent holders and accused infringers, which in fact does little to advance justice. Third, the threat of damages, based on a very low threshold, creates an enormous point of leverage for companies to settle cases, even when the underlying patent does not merit settlement. We believe that Congress should change these provisions to make it clear that punitive triple damages should be imposed only when there is evidence of, as the Supreme Court recently stated, egregious conduct. All other proposals that we have seen will just result in letters that provide somewhat more specific notice to the accused party, with no reduction in the litigation over this issue.

A second element of damages is also in need of attention by Congress. Today, when a small component of a large and successful product is found infringing, the damages that are assessed may be based not on the value of the infringing component, but on the value of the product as a whole. This has led to a number of situations of gross unfairness. We believe reform is needed to make sure courts calculate damages on the value of the component (the spell checker and not the spreadsheet, the cup holder and not the car) rather than on the value of the larger product.

Third, the way in which the courts have interpreted the law in granting injunctions has also led to disruptions for computer and software companies -- notwithstanding clear statutory language that injunctions are to be granted based on a weighing of the equities. The patent law specifically requires a balancing of "equities" before granting injunctions as a remedy, but the courts are interpreting this requirement very narrowly. The jurisprudence in this area over the past 50 years, clearly different from the way the patent law was interpreted for the first 150 years, has evolved in ways that no longer fully balances those equities. Most recently, in the eBay opinion issued just weeks ago, the

CAFC ruled that the sole reason for not granting an injunction is a national health emergency. That interpretation of the “public interest” ignores a great breath and body of law, and turns the concept of equity into a pinhole that no case involving computers and software can possibly thread.

The net result is substantial disruption in the marketplace. In part, this is a consequence of the fact that injunctions are granted with respect to an entire product incorporating the infringing invention, not just the element. We have had three major cases in just the past several weeks. The Sony PlayStation console was enjoined because a joy stick was infringing; Rim’s Blackberry was enjoined because a synchronizing component was infringing (this case has now been settled.); and finally, eBay’s business is now at risk because it may incorporate an infringing element. As our colleague from General Motors noted, we now have a case of someone wanting to enjoin the sale of pick-up trucks because they contain a built in beer cooler that is claimed to be infringing.

Today, too many plaintiffs are gaming the system to force very large settlements by filing suits in plaintiff-friendly jurisdictions like the Eastern District of Texas. Their leverage is the threat of obtaining monetary damages that are disproportionately large, or of obtaining triple damages where there has been no evidence of conduct warranting a punitive measure of damages, or of obtaining injunctions that could shut down major production enterprises. This presents a U.S. based company with a Hobson’s choice of deciding whether to settle the matter at a hold-up price or run the risk of having its products shut down. These practices have to be addressed by creating disincentives to filing these types of “gaming the system” suits.

We recognize that not all industries that rely on patents face these threats. We are mindful of the concerns of some groups that these solutions to litigation issues not disrupt monetary and injunctive relief for appropriate cases. We agree with this concern. Any solution must address the problem narrowly, without creating unintended disruptions in other areas. And, of course, any solution must also be consistent with international norms and obligations.

Interlocutory Appeals

Under current law, a party may appeal all or part of a court's ruling on claim interpretation only after a final determination in the case, and usually after incurring substantial additional litigation costs. To address this problem, we recommend that Congress create a right for an interlocutory appeal for either party to patent litigation, regarding all or part of a court's ruling on claim interpretation. Thus, for example, either party may immediately appeal a decision on claim interpretation to the Court of Appeals for the Federal Circuit (CAFC), while having the proceedings in the lower court stayed until a decision on the appealed issues is made by the CAFC.

Conclusion

We thank you for the opportunity to appear before you today, Mr. Chairman, and we look forward to working with this Committee to find ways to make our patent system even better.

