Testimony of

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SUMMARY OF STATEMENT OF CARL E. GULBRANDSEN

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF, on whose behalf I appear. WARF is the patent management organization for the University of Wisconsin-Madison ("UW-Madison"). Founded in 1925 and one of the first organizations to engage in university technology transfer, WARF has had a significant impact on advances in scientific research and the welfare, health and safety of people in Wisconsin, this country and worldwide and is a recipient of the 2003 National Medal of Technology.

In 1980, under the leadership of this Committee, Congress enacted the Patent and Trademark Law Amendments Act (commonly known as the Bayh-Dole Act), incorporating into law the cardinal principle that the public benefits from a policy that permits universities and small businesses to elect ownership of technology invented with federal funding and to become participants in the commercialization process. Today the list of inventions by individuals employed by U.S. universities is impressive. As patent owners, universities depend on a high quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer occurs and the public benefits. If the system is weakened, the public benefits are reduced.

The current debate about patent reform is subdivided into two categories: patent quality improvements and litigation reform. In regard to quality issues, the first line of defense against poor quality patents and slow decision-making is to provide the USPTO the fiscal resources that it needs to hire and train skilled examiners and implement effective electronic processing capabilities. Further steps remain. Diversion should be permanently barred. The USPTO should continue to implement its "Strategic Plan," which it can do in significant part through regulatory and administrative means. Several elements of the Strategic Plan require legislation: for example, expanding the early publication of patents at 18 months and assignee filing. WARF also supports the creation of a limited post-grant opposition procedure, with reasonable time limitations and no second window, full disclosure of the real party in interest, a broader range of the estoppel effect of the opposition, and support for the USPTO to implement without compromising its ability to examine and issue high-quality patents. WARF additionally opposes dramatic changes to continuation practice.

In regard to litigation reform, including modification of the current law relating to injunctions and damages, the Subcommittee should pay careful heed not to retard the success of university technology transfer and the creation of vibrant new university spin-out companies. WARF therefore opposes injunctive relief reform and the expansion of prior user rights. Finally for the benefit of universities and independent inventors, and to preserve our country's technological lead, WARF would prefer that the first-inventor-to-invent system be maintained. Nonetheless, WARF recognizes that some benefits may be gained by harmonizing the U.S. patent system with the European and Japanese patent systems. However, certain statutory safeguards should be included.

STATEMENT

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the topic of "patent law reform: injunctions and damages." Thank you also for an important piece of legislation (the CREATE Act) processed into law last Congress under your leadership and that of Senator Leahy and several Committee cosponsors, including Senators Kohl, Feingold, Grassley and Schumer. Science today depends on collaborative research, and the CREATE Act will stimulate numerous inventive activities in the future.

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management organization for the University of Wisconsin-Madison ("UW-Madison"). I am making my statement today on behalf of WARF.

In addition to serving as Managing Director of WARF, I was recently appointed by the Secretary of Commerce to the Patent Public Advisory Committee of the United States Patent and Trademark Office ("USPTO"). I am also Vice President of the Public Policy Committee of the Association of University Technology Managers ("AUTM"). Finally, as a patent practitioner with over twenty years of experience in the private sector, I served as General Counsel of Lunar Corporation, a medical imaging company in Madison, Wisconsin; in law practice, I prosecuted patents and also litigated patent infringement cases representing independent patent owners and small businesses; and, as an adjunct faculty member, I have taught patent law at the University of Wisconsin Law School.

I. Background about WARF

WARF was founded in 1925 and is one of the first organizations to engage in university technology transfer. It exists to support scientific research at the UW-Madison and carries out this mission by patenting university technology and licensing it to the private sector for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research. Over the past 80 years, WARF has contributed approximately $750 million to UW-Madison to fund basic scientific research.

WARF's technology transfer successes have had a significant impact on advances in scientific research and has had profound and positive effects on the welfare, health and safety of people in this country and worldwide. Included among UW-Madison inventions patented and licensed by WARF are: Professor Harry Steenbock's invention of Vitamin-D, which essentially eradicated rickets as a childhood disease; Professor Karl Elvehjem's copper-iron complexes, which improved the physiological assimilation of iron in humans; Professor Karl-Paul Link's discovery of Coumadin®, the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide worldwide; Professor Charles Mistretta's digital vascular imaging technology, which enabled accurate diagnosis of blockage of the vessels of the heart; and Professor Hector DeLuca's Vitamin-D derivatives, which are widely used to treat osteoporosis, renal disease and other diseases. Year-by-year, the UW-Madison ranks in the top ten universities in terms of patents granted by the USPTO. As recognition of its excellence in technology transfer, WARF received in March of this year the National Medal of Technology, the highest award that can be conferred by the President of the United States to individuals and organizations making significant and lasting contributions to the country's economic, environmental and social well-being through the development and commercialization of technology. WARF is the first university technology transfer office to receive this prestigious award, and I was proud to accept this honor personally from President Bush in the East Wing of the White House. Mr. Chairman, I believe that the honor bestowed upon WARF by the President is recognition by our government of the importance of university research and technology transfer to the economic health and well-being of our country. It is from this viewpoint that I am here testifying.

II. University Patent Licensing

To understand WARF's position - and that of many other university technology transfer offices - on patent law reform, an understanding of university patent licensing is necessary. We share the fundamental belief that the Founding Fathers recognized not only the need to protect the rights and property of individual Americans, but also the significance of providing incentives to stimulate the economic and cultural growth of the country. The U.S. Constitution (in Art. I, § 8, cl. 8) authorizes the Congress "[t]o promote 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." Congress may therefore encourage the toils of inventors and authors by protecting their rights to reap fruits from their labors. It did not take the federal government long to act. In his first annual message to the Congress, President George Washington reminded legislators of the importance of progress in science and the arts, observing that "there is nothing which can better deserve your patronage than the promotion of science and literature." Less than six months later, the First Congress passed the first Patent Act, which President Washington signed on April 10, 1790. In 1990, on the occasion of the bicentennial anniversary of the first patent act, President George Bush issued a proclamation stating that the patent law, as it enters its third century, should be recognized for the role that it has played in the scientific and economic development of our country. In the interim, Americans have touted the successes of the U.S. patent law not only domestically but also internationally, asking developing countries to follow us. We have also upgraded our patent laws whenever necessary.

In 1980, under the leadership of the Senate Judiciary Committee, Congress enacted the Patent and Trademark Law Amendments Act (commonly known as the Bayh-Dole Act). See 35 U.S.C. §§ 200-212. Mr. Chairman, although the Act is named after Senators Bayh and Dole, you and other Senators played a positive role in the Act's enactment. This Committee drafted into law the cardinal principle that the public benefits from public policy that permits universities and small businesses to elect ownership of technology invented with federal funding and to become

participants in the commercialization process. After passage of the Bayh-Dole Act, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions.
In 1980, approximately 25 U.S. universities had technology transfer offices and no uniform federal patent policy existed. Today, more than 230 U.S. universities have such offices. In 1980, only a handful of patents were granted to universities. Today, universities are recipients of approximately four (4) percent of U.S. patents. This success has its roots in the Bayh-Dole Act.
Today, the list of university inventions is indeed impressive. This list includes, among others, the following:
? Leustatin, a chemotherapy drug: Brigham Young University;

? Solution for the preservation of organs for transplant: University of Wisconsin - Madison;

? Lithography system to enable the manufacturing of nano devices: University of Texas - Austin;

? Rheumatoid arthritis relief: University of California - San Diego;

? Effective Aneurysm Treatment: UCLA;

? Water-repellent cotton fabric using nanotechnology: University of Oklahoma;

? Genetic-modified soy beans resistant to aphids: University of Illinois; and

? Synthetic penicillin: Massachusetts Institute of Technology ("MIT").

For a listing of more university innovations, see AUTM Licensing Survey: FY 2003.
These inventions, and many others, affect Americans in their daily lives, whether as hospital patients, farmers, employees in large and small businesses, scientists, students and entrepreneurs. The inventions stimulate the creation of start-up companies and new jobs, often for university graduates. For example, in 2004 the University of Pennsylvania formed 14 new companies. The Bayh-Dole Act, so instrumental in the successful transfer of university technology to industry, is predicated on the conviction that universities must be able to pursue their mission of creating and disseminating knowledge in an open environment and, concurrently, protect their inventions through strong intellectual property laws. As patent owners, universities depend on a high quality patent system that promotes certainty and confidence, and permits the enforcement of exclusive rights. If that system is strong and robust, technology transfer occurs and the public is benefited. If the system is weakened, the public benefit is reduced.
Based on our initial analysis of a plethora of patent reform proposals on the table, WARF is able to express support for some. However, several of the reform proposals represent a step backward for university patenting and commercialization efforts. Candidly, these proposals could be described as "anti-patent." Many of them fall into the category of diminishing enforcement rights and remedies of patent holders and have little bearing on improving patent quality. I believe that their passage would thwart the tremendous successes that universities have experienced in innovation. Economic development, small businesses and jobs could be jeopardized in every state of the union.
III. Support the Needs of the USPTO

In the past two decades, intellectual property assets have become vital to the performance of the U.S. economy. Continuing high rates of innovation and inventiveness are reflected in the patent law system, wherein patent grants are actively sought administratively, exploited commercially in the marketplace, and vigorously enforced in the federal courts. Since 1992, the number of applications in the USPTO has more than doubled to 400,000 applications annually (in fiscal year 2004) and, in 2005, the USPTO issued more patents than it did during the first four decades of American history. High quality patents serve as a measure of success. However, in recent years the patent office has been challenged financially and administratively resulting in an increase in pendency of applications and an occasional lapse in the quality of examination. These stresses on the patent office for the user translate into delays in negotiating and obtaining licenses to the pending applications and increases litigation costs when poor quality patents issue.
The first line of defense against poor quality patents and increasing patent pendency is to provide the USPTO the fiscal resources that it needs to hire and train skilled examiners and implement effective electronic processing capabilities. The initial step of providing the USPTO with adequate resources (with a temporary bar to fee diversion)

was already accomplished last Congress in the Patent Fee Modernization Act. WARF supported that Act.
Further steps remain. Diversion should be permanently barred. In addition, the USPTO should continue to implement its "Strategic Plan," which it can do in significant part, through regulatory and administrative means. Several elements of the Strategic Plan require legislation, some of which are included are on the legislative table: for example, expanding the early publication of patents at 18 months and assignee filing. WARF supports these proposals. Finally, as is suggested in "A Patent System for the 21st Century," A Report of National Research Council of the National Academies ("NAS Report"), the USPTO should create an internal, multidisciplinary capacity to assess management practices and proposed changes, including an early warning system for new technologies. The House and Senate Judiciary Committees can also continue to play an important oversight role.
The patent law system, like a patient in a doctor's office, needs to make certain lifestyle changes, but radical surgery is not necessary or required. Exercise of the "power of the purse" and vigilant oversight by the legislative branch, and administrative reforms by the executive, should serve to alleviate the need for some of the more radical reforms in the Patent Act of 2005.
IV. A Threat to University Technology Transfer
WARF supports a number of patent reform proposals as being beneficial for university technology transfer. Some changes to those proposals, however, are necessary. Most significantly, WARF supports a limited post-grant opposition procedure, with the addition of appropriate curative amendments. Included in these amendments would be reasonable time limitations, no second window, full disclosure of the real party in interest, a broader range of the estoppel effect of the opposition, and support for the USPTO to implement without compromising its ability to examine and issue high-quality patents.
As presently drafted, the post-grant opposition provision of a recently introduced House bill (H.R. 2795), coupled with the removal of the estoppel effect afforded to reexaminations, will result in a university patent owner facing multiple third-party patent challenges. A university could be forced to address the same issues regarding patentability during reexamination, post-grant opposition, and then litigation, all at significant expense. Every trial lawyer knows that litigation expenses are tied to remedies. Often in the face of escalating costs, a legitimate patent holder will abandon exclusive rights rather than fight a protracted battle to secure protection for intellectual property. Uncertainty about the rights secured through an issued patent will make licensing technology to the private sector for commercial development significantly more difficult for universities, thereby delaying the transfer of technology from lab to application and thwarting one of the primary purposes of the Bayh-Dole Act. For start-up companies, uncertainty will make it more difficult to attract investment dollars. Accordingly, the estoppel effect afforded reexamination should be maintained and certain limitations should be incorporated into the post-grant opposition process in order to stem abuse, avoid undo delays, and protracted uncertainty relating to the scope of patent protection.
WARF is grateful to you, Mr. Chairman and Mr. Ranking Member, for your sterling leadership last Congress on enactment of the Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Public Law No. 108-453. The CREATE Act is implicated in the proposal to establish a first-inventor-to-file system in the United States. I ask that you ensure that the CREATE Act be preserved and any CREATE Act amendments have the same effective date, same legislative history and same USPTO rule-making authority as Public Law No. 108-453.
A number of patent reform proposals are designed to reduce the equitable and monetary remedies currently available to patent holders. These proposals, if enacted, would retard the success of university technology transfer and the creation of vibrant new university spin-out companies. Universities are dependent on enforcement rights because a patent, in order to be licensed successfully to the private sector for commercial exploitation, must be strong enough to stimulate necessary investments. WARF therefore has grave concerns about the following subjects.
1. Injunctions. Several proposals contain a tilting of the playing field in favor of infringers over the interests of universities, small businesses and start-up companies. For example, Section 7 of H.R. 2795 requires a court to stay the injunction pending an appeal upon an affirmative showing that the stay would not result in irreparable harm to the patent holder and that the balance of hardships from the stay does not favor the patent holder. This language, portrayed as a compromise, will result in appeals being made in most, if not all, patent infringement cases increasing the expense and in most instances, severely decreasing the benefit of the bargain the inventor makes with the government to obtain the right to exclude others from making, selling and using the invention in return for disclosing the invention to the public.
The right to exclude others from using the invention is fundamental to the patent bargain. A presumption in favor of injunctive relief is built into the process of patent infringement currently for good reason - injunctions respect this fundamental right to exclude. Any limits to injunctive relief simply create incentives to infringe and to prolong litigation and, in fact, will potentially spawn additional litigation because companies will choose to forego up-front licensing and instead wait for a lawsuit to create what would be, in effect, a compulsory license. Such a situation would be especially difficult for universities because many are resource constrained and would have difficulty diligently pursuing their rights through litigation. In addition, the proposed changes would curtail the efforts of university spin-

out companies to secure funding and develop innovative products and medicines because infringers will have less incentive to respect the patent rights of such companies. Consequently, investors will have less incentive to fund such innovative companies. This inevitable cooling effect on innovation would be particularly unfortunate considering that much of the success in promoting economic development through the Bayh-Dole Act has resulted from the successes of university spin-outs and small businesses.

2. Monetary Damages. A number of proposals exist to diminish the amount of monetary damages that can be obtained by patent holders that have been infringed. These proposals can be subdivided into two parts: reducing damages for "willful infringement;" and calibrating damages to the portion of the realizable profit that should be credited to the inventive contribution as compared to features of improvements added by the infringer.

WARF recognizes that patent litigation is costly and risky. The escalation of patent litigation is also worrisome. The Committee would be well-advised to analyze why patent litigation is burgeoning. If rooted in increasing infringements, then the problem is not fixed by reducing monetary damages. Moreover, as Dean Kamen has correctly observed, strengthening the quality of patents will do more to stem frivolous litigation than reducing the damages available to patent owners for infringement of their inventions. And, as pointed out above, the best way to improve patent quality is to provide the USPTO the tools that it needs.

Some benefits can be gained by modifying or eliminating entirely the subjective elements of litigation: for example, whether someone "willfully" infringed a patent or whether a patent application included the "best mode" for implementing an invention. However, tinkering with willful infringement or requiring judges to calibrate damages by weighing the portion of a product or process infringed as against the whole unnecessarily tie the hands of federal judges and deprive the patent owner of the full measure of consideration of unlawful use of his/her patented technology.

3. Prior User Rights. The proposed statutory expansion of prior user rights does not per se affect injunctions and damages. Prior user rights establish a general defense against infringement. WARF opposes the proposed expansion. Expanded prior user rights will encourage innovations to be kept as trade secrets, a practice which is contrary to the fundamental premise of the U.S. patent system which rewards and encourages disclosure. Prior user rights deprive patentees of the benefits of their bargain. Because patentees disclose, they are entitled to exclusive rights in the invention. By increasing the ambit of trade secrecy, inventors (especially those in the private sector) will be more inclined to opt for trade secret protection over patent protection, thereby diminishing the importance of the patent system. Mr. Chairman, the expansion of prior user rights is a "sleeper" issue that deserves the careful consideration of the Subcommittee.

4. Limitations on Continuation Practice. Although not related to injunctions and damages, WARF opposes limiting continuation practice and believes such a change in the law would negatively impact universities and research laboratories. WARF, however, would support rulemaking authority in the USPTO to prevent abusive practices by patent applicants on continuation applications. University research is early-stage research and the inventions coming from university research are most often not fully defined. Because of this, universities rely on filing robust initial applications that can be made more specific through additional claim language as the usefulness of a given discovery manifests itself, requiring that patent applications contain the broadest claims possible at the outset of prosecution will, in many instances, result in the real invention being lost. The loser in this "bet it all on the first roll" requirement is the public. The public deserves the benefit of the best inventions harvested from the supported research. Because university research is early stage the flexibility to broaden claims through continuation practices is needed to identify the best invention to the public good.

5. First inventor to file. The first-inventor-to-file system that exists in the rest of the world is a disadvantage to universities and independent inventors. Let me read what ProTon, the pan-European network of knowledge transfer offices has said about the European patent system. "The patent system in Europe, with its complexity and cost, is much less appropriate to university-based inventions than the U.S. system and acts as a barrier to innovation from public research. It lacks a grace period, a provisional patent system, a continuation-in-part (CIP) system and is several times more expensive. ProTon Europe is convinced that these differences account in large part for the much lower number of patented inventions coming out of public research in Europe." (Industry & Higher Education, February 2005, page 6.) I believe that one of the reasons the United States is a technological leader is because we have a first-to-invent system. The first-inventor-to-file proposal would be a hardship for a vast majority of universities. Universities are open environments and universities rely on the advantage given to the true inventor by our present patent law system. Universities cannot afford a race to the USPTO.

For the benefit of universities and independent inventors and to preserve our country's technological lead, WARF would prefer that the first-to-invent system be maintained. Nonetheless, WARF recognizes that some benefits are gained by harmonizing the U.S. patent system with the European and Japanese patent systems. If we must harmonize, bear in mind that our system has certain advantages that must be preserved and are critical to our ability to innovate. After all, the U.S. is the world's leader in innovation.

For example, certain statutory safeguards are necessary. Such safeguards should include the means to promote public disclosure of new discoveries, maintain the blanket one-year publication rule that currently provides a one-year grace period, and protect the true inventor from misappropriation by parties who have not made a significant contribution to a claimed invention. Any legislation should therefore, at a minimum, require an applicant to take an oath that he/she is an inventor or has been assigned the right to patent a given technology by the inventor and not leave such a determination to the discretion of the Director of the USPTO. In addition, the duty of candor imposed by patent law should specifically prohibit the misrepresentation of inventorship. Although a change to a "first-inventor-to-file" system would move U.S. patent practice closer to that of much of the rest of the world, any change to U.S. patent law still must recognize that under U.S. law and consistent with the U.S. Constitution, the right to patent goes to the inventor.

V. Related Issues

The Bayh-Dole Act is widely recognized as successful beyond all expectations. It has been, and continues to be, an essential component of U. S. global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about Bayh-Dole and express the wish that their own countries would adopt such forward-thinking legislation. In fact, Japan's recent changes to its patent law were modeled on that of the U. S. Bayh-Dole Act. The Senate Judiciary Committee should be proud of the role it played in passing such successful, landmark legislation. Now in its 25th year, we should think of ways to celebrate the Act's successes. However, despite the undisputed successes of the Bayh-Dole Act, there are continued attempts to alter the Act either directly or indirectly. For example, a majority of the patent reforms before you chip away at the value of university patents for the benefit of others and, thereby, diminish the good that can come from university technology transfer. I trust that this Subcommittee in its wisdom will preserve one of its most important legacies and oppose any legislation that compromises the demonstrated success of Bayh-Dole and its pivotal role in improving the welfare, health and safety of people in this country and worldwide.

VI. Conclusion

In closing, the subject of "patent law reform: injunctions and damages" goes to the heart of the matter: the ability of patent holders to enforce their exclusive rights in the courts. As observed by Professor Jaffe, "reforming the litigation process while protecting patent rights is a tricky business." (Adam B. Jaffe, "The State of Change," IP Law and Business 28, 30 (June 2005). I leave you with three cautionary recommendations:

? Unless a strong and compelling showing is made that change is necessary, maintain the patent law as it is presently enacted.

? If the legislation is to move forward, please focus on measures that promote patent quality and not on proposals to weaken the patent law.

? Continue to protect university ownership of patents and technology transfer from erosion by amendments (either direct or indirect) that compromise its demonstrated successes.

The June 13, 2005, issue of Business Week features a cover story entitled "Biotech, Finally," detailing that biotechnology has finally come of age. The biotech revolution is actually an evolution that started on university campuses. According to the article, "it evinces the slow accumulation of decades of research" by academic researchers who pushed biotech forward. The endless cycle of academic research, technology transfer, collaborative research, and commercialization of cures by the private sector continue today into a golden age of drug discovery. Now is not the time for radical surgery to the patent law.