Testimony of

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HEARING ON PATENT LAW REFORM: INJUNCTIONS AND DAMAGES

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Before the Subcommittee on Intellectual Property
of the Senate Judiciary Committee

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Mr. Chairman and distinguished Members of the Subcommittee,

My name is Jeff Kushan. I am a partner in the Washington office of the law firm of Sidley Austin Brown and Wood, LLP. I am also a registered patent attorney, and specialize in the areas of biotechnology, pharmaceuticals and software-related inventions.

I have been asked to testify today based on my experiences working with companies in the life sciences sector. I am pleased to offer views that reflect my experiences with such companies, but note that I am testifying today in my personal capacity, and the views I offer are my own.

Introduction

Patent law reform has become an active issue in the past few years. One reason for this is that patents have grown in importance to several industrial sectors which traditionally have not been significant users of the system, including the software, e-commerce and financial services industries. A second is that the workload of the Patent and Trademark Office (PTO) has continued to grow at a significant pace against the backdrop of an uncertain funding picture. This has raised concerns over the capacity of the PTO to issue valid patents in a timely fashion. And, recently, comprehensive studies of the patent system and its operation have been conducted by the National Academies of Science and the Federal Trade Commission. These studies recommend a number of significant reforms to the patent system, and have spawned extensive discussion and debate within the patent community.

Comprehensive patent law reform, however, is not a new topic to this Committee. Between 1995 and 1999, this Committee played a central role in shaping reforms to the patent system that ultimately were enacted as the American Inventors Protection Act of 1999. Those reforms followed changes enacted in 1995 as part of the effort to implement the Uruguay Round Agreement creating the World Trade Organization. Each of these reforms has had a significant impact on the patent system, making it more transparent and effective.

Today's patent reform debates are motivated by the belief of many companies that there is too much uncertainty and unpredictability involved in the patent system. This is true from both the perspective of companies that wish to enforce patents, and from those who must face patents. Another motivation is the perception that the PTO is struggling to keep pace with its workload. The package of reform measures now under consideration reflects some effort to respond to each of these motivating factors.

Before addressing those measures, however, it is important to recognize two of the most significant challenges facing our patent system today.

First, the PTO faces serious challenges in performing its statutory function of issuing valid patents in a timely fashion because of the ongoing problem of patent fee diversion to other government entities. The unpredictable nature of patent fee diversion has made it difficult for the PTO to engage in the long-term restructuring of its operations that is necessary to make the patent examination process more reliable and efficient. Without question, the most important legislative deliverable for Congress in the effort to improve the patent system is predictable and adequate funding for

PTO operations. And, as Congress contemplates granting the PTO more responsibilities, predictable and adequate funding will become even more important.

Second, the model used by the PTO to conduct examination of patent applications needs to be seriously reevaluated. Every application that is filed today is placed into the queue for examination. This requires the PTO to budget for and engage in an unnecessary examination of many thousands of patent applications. The United States is unique in the world in this respect - every other major office conducts examination of applications only upon request and payment of a fee. Exacerbating this problem is the approach the PTO employs in "restricting" patent applications. The PTO requires applicants to file additional patent applications when it believes a first application has claimed more than one patentably distinct invention. The PTO examiners, however, use an exceedingly narrow and strict standard for restriction in the biotechnology sector, which has led to a multiplicity of unnecessary filings. These extra applications make coherent and efficient examination of inventions very difficult, and contribute to an artificial backlog of unexamined applications. Restructuring the patent examination process to address these two problems would result in examiners having more time to examine each invention, and would thus significantly improve patent quality. Congress should consider legislation to address both of these issues in conjunction with the current effort to reform patent standards.

As noted above, the primary motivation for patent law reform is the concern of many companies over the unpredictability of the process of resolving disputes over patents through litigation in the Federal Courts. This concern extends to companies in all technology sectors, including the biotechnology and pharmaceutical sectors. Although the Court of Appeals for the Federal Circuit has done much over the years to clarify the requirements and standards for patentable inventions, there still remains a significant amount of uncertainty in how those requirements and standards will be applied to biotechnology inventions by trial courts and juries. As a result, it remains difficult to predict if a patent will be held valid, if it will be infringed or if it will be held unenforceable. Similarly, it is often impossible to predict what consequences and damages a company will face if it is found to infringe a patent. The uncertainty in today's patent litigation environment, unfortunately, is being exploited by certain patent owners to distort the value of their patent rights and to undermine the legitimate use of patents. Reforms to the patent system- both as to the standards governing patent validity and as to outcomes and consequences in litigation - are necessary and timely.

Over the past few months, in hearings before this Committee and in the House, a relatively focused set of reform measures have been identified. Recently, Chairman Smith of the Subcommittee on Courts, the Internet and Intellectual Property of the House Judiciary Committee recently introduced legislation, the Patent Act of 2005, H.R. 2795 (the "House bill"), which incorporates many of these reform measures. The House bill would make a number of significant changes to the patent system.

- It would change our system to provide that patents are awarded to the first inventor who files a patent, rather than necessarily the first who invented the invention. In conjunction with this change, reforms are made to the standards that define prior art, along with changes to delete a number of subjective elements found in the current patent statute.
- It would create an administrative procedure that the public could use to review the validity of patents. This post-grant opposition system would be administered by the PTO, and would be a more rigorous administrative alternative to litigation than what is presently available at the PTO.
- It would create a new procedure that the public could use to cite prior art before a patent issues.
- It would change how allegations of inequitable conduct could be raised and addressed in litigation, and vest the PTO with more authority to evaluate and sanction parties that engage in misconduct before the PTO.
- It would codify certain standards that govern determinations of damages where the patent concerns one component of a product that has many components.
- It would alter the standards that govern determinations of willful infringement, and how and when such allegations could be raised in litigation.
- It would give the Director of the PTO the authority to regulate so-called continuation practice, to prevent abuses that are perceived to exist.

Many of these measures are supported by most sectors of the patent community. Others are supported in principle with differences existing as to how the measure should be implemented. If enacted, these measures would significantly improve the patent system, provided that certain significant questions are addressed and resolved.

The legislative package reflected in H.R. 2795 also includes a number of problematic measures, including, in particular, a proposal that would alter the standards that govern injunctive relief in patent cases. Reforms that raise questions as to whether a patent owner will be able to prevent the unauthorized use of a patented invention, particularly after the patent has been fully adjudicated and found valid and infringed, will cause significant harm to the biotechnology and pharmaceutical sectors. Such reforms should not be included in any legislation that is designed to reflect a consensus reform package that will benefit all industries that use the patent system.

I note that other problematic measures have been raised in public debates on patent reform have not been

incorporated into the bill. One such measure would have courts use a less stringent evidentiary standard to adjudicate attacks on the validity of a patent when the evidence at issue concerns information that was not considered in the original examination of the patent. Lowering the evidentiary standards courts use to adjudicate challenges to patents will vastly complicate litigation over patents, and create unacceptable risks to companies in the biotechnology and pharmaceutical sector. Like measures that would change injunctive relief standards, these types of changes should not be included in any legislation portrayed as being a consensus package of reforms.

Ultimately, patent law reform will be successful if, after the reforms are enacted, the patent system is clearer and more transparent in its operation. If the reformed system makes it easier for patent owners and third parties to determine which patents are valid, which are not, and what actions will infringe the patents, all users will benefit. Congress should use this perspective to determine which measures it will incorporate into legislation.

I would like to focus my testimony on the issues that I believe raise problems that either cannot be resolved, or which can be resolved only through careful attention to the different business models that govern different sectors of the patent user community. These are standards governing injunctive relief, the proposed post-grant review procedure, continuation practice, and standards governing award of damages, including willful infringement.

A Life Sciences Perspective on Patents

The patent system is credited with being a key factor in the birth and continuing success of the U.S. biotechnology industry. The 1980 Supreme Court decision of Diamond v. Chakrabarty held not only that man-made organisms are eligible to be patented, but that exclusive rights could be obtained in such organisms and the products they yield. The promise of patent exclusivity, combined with an intense period of scientific advancement and the availability of eager investors in the early 1980's, led to a surge of investment in biomedical science that can be fairly credited as launching the biotechnology industry.

The formula for opportunity and investment that these early innovators and investors saw then is the same one that today's innovators and investors see. Specifically, the guarantee of patent exclusivity drives decision making on funding, decisions on research priorities, and decisions on product development. Patent exclusivity enables a company to justify making significant investments, and taking significant risks, in a multi-year effort to develop and bring new drugs to market.

Effective patent exclusivity means, among other things, that the innovator of a new drug or biological product, will be able to enjoy a period of time where the only competition that innovator will face will be from different products. In the biotechnology and pharmaceutical sector, the time it takes to go from invention to launch of a product routinely exceeds a decade, and often can take more than fifteen years. Patent applications for these inventions are typically filed and the patents issued early in this process, meaning that these innovators have only a short period of time at the end of the life of a patent in which to earn revenues on their new product. The capacity of the patent owner to prevent market entry by products that infringe the patent, thus, is paramount to the decision-making process that guides investments that occur years before the patent owner's product is on the market, and often before it can be visualized.

In the course of developing a biotech or pharmaceutical product, companies often will make significant discoveries and develop additional inventions that may prove critical to making the drug a safe and effective product. These improvements can lie in the area of techniques for manufacturing the product on a sufficient scale without impurities, in preparing drug delivery systems, particularly for chronic or difficult diseases, or in improving the potency and eliminating side effects of a new active ingredient. Patents are sought for these additional inventions as well as for the pioneering work, because they each are essential to ensuring that the product that reaches the market will be effectively protected.

The profile of a life science company's dependence on patent protection is distinct from the way that patents are used and encountered by companies in other industries. For example, in the software field, a single product might incorporate hundreds or thousands of discrete and relatively minor inventions. Those products evolve continuously, and incorporate on an ongoing basis numerous and evolving incremental innovations. Certainly, significant inventions are made and patented in all industries, including the software industry. However, in contrast to the biotechnology and pharmaceutical sector, the window of product development and evolution is shorter and more constant in the software field, and products launch in that industry with a much shorter lead time.

These and other distinctions are important to appreciate in debating patent law reform. The options available to change standards and operation of the patent system must be considered in view of the necessity of maintaining the technology-neutral nature of the law. The Congress must carefully study the nature of problems that different industries identify, and the solutions proposed by those industries. The reason is simple - changes that would "solve" one industry's "problems" could create immense problems for other industries based on the different way patents operate in those other industries. In the life sciences sector, changes to the system that raise questions about the ability of a company to obtain effective patent protection for its products in development, or which raise questions about whether the company will be able to prevent the marketing of infringing products, fundamentally conflict with

the business model of the industry. As such, changes of that character - particularly changes to injunctive relief standards - are viewed as major problems.

Proposed Reforms to Standards for Injunctive Relief

In the House bill, and in recent debates, proposals have been made to alter the standards that govern the grant of permanent injunctive relief in patent cases. In particular, Section seven of the H.R. 2795 would fundamentally alter the nature of a United States patent by altering the standards governing entitlement to permanent injunctive relief under section 283.

Two specific changes are proposed in the House bill. The first would alter section 283 to include a sentence requiring that courts consider the fairness of injunctive relief in light of all the facts and relative interests of the parties. The second change would direct District courts to stay the effect of judgments awarding permanent injunctions pending appeal if the infringer can establish that no irreparable harm will be caused to the patent owner during the pendency of the appeal.

The first amendment seeks to change the standards that courts employ to evaluate requests for the grant of permanent injunctions once a patent has been found valid and infringed. In particular, the change appears motivated by a desire to create new jurisprudence in the patent law that would permit additional scenarios, if proven, to justify the refusal of a court to grant a permanent injunction against an infringer.

Historically, the standards governing entitlement of a party to injunctive relief in situations other than patent cases have been cast in more general terms than those traditionally articulated as governing patent cases. General injunctive relief standards require a federal court, applying traditional standards of equity, to determine that the party seeking the injunction establish that a legal remedy would be inadequate to compensate the harm that has been caused, and that the harm in question is irreparable damage to the party seeking the injunction. See, Meredith v. City of Winter Haven, 320 U.S. 228, 235 (1943); Weinberger v. Romero-Barcelo, 456 U.S. 305, 311 (1982). Injunctive relief, thus, is not routinely awarded to parties seeking the injunction, even when the party prevails on its cause of action.

Courts in patent cases, however, routinely grant injunctive relief once the patent owner has established that the patent is valid and infringed. This is not because patent cases are fundamentally different, or that the courts bypass the usual equity-based analysis. Instead, it is because courts have routinely and consistently held that the harm caused by infringement of the patent is unique, and often will cause irreparable damage to the patent owner that cannot be remedied by money damages. As such, in applying the general injunctive relief standards, courts routinely have found circumstances that justify the grant of injunctive relief for a patent owner.

The Federal Circuit has acknowledged that its application of the general standards in patent cases means that a prevailing patent owner, more often than not, will be granted injunctive relief. It has done so not by finding the general equitable rule to be inapplicable to patent cases, but by finding that its application in patent cases compels in most instances the award of injunctive relief. As it observed in Roche Prods., Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858, 866-67 (Fed. Cir. 1984):

[I]f Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language rarely if ever to be expected from a body itself made up very largely of American lawyers, having, probably, as much respect for traditional equity principles as do the courts. If an injunction was not mandatory in Hecht Co. v. Bowles [involving a statute that specified circumstances where an injunction "must" issue, but circumstances in which an injunction would have been "repugnant"], the more permissive statutory language [of 35 U.S.C. § 283] makes it a fortiori that an injunction is not mandatory now.

The strong bias in section 283 and in the patent jurisprudence in favor of a patent owner obtaining an injunction thus is based on sound public policy. Unlike physical property, which can be defended against trespass through a variety of non-judicial means (e.g., building a fence, guarding the boundaries of land, safekeeping of a valuable item of personal property), the trespass of an intellectual property right can be prevented only through the grant of an injunction issued by a court. Also, unlike real property, the trespass of an intellectual property right often will destroy the entirety of the property interest. In other words, if one cannot stop an infringement of a patent, there often will be no residual value left in the patent property.

As such, courts have frequently equated the value of a patent with the capacity of its owner to enjoin unauthorized use of the patented invention. "Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research." Moreover, U.S. courts have long recognized that appropriate remedies for patent infringement must take account of the unique nature of the harm suffered by the patentee by an infringement of the patent property right. The right to exclude others from the unauthorized use of the patent property (i.e., the patented invention) thus has been labeled the hallmark of the ownership interest in a patent. "The right to exclude others from a specific market, no matter how large or small that market, is an essential element of the patent right."

The justification offered by those seeking changes to the permanent injunctive relief standard is the unpredictability and uncertainty of patent litigation. In particular, companies have expressed concerns over their inability to predict what consequences will ensue from a district court finding that a patent is valid and has been infringed.

A specific concern has been the situation where the infringer is marketing a product, and the patent owner is not, yet injunctive relief is sought to enhance the exposure of the infringer. By doing so, the infringer faces a very difficult choice - a significant business disruption with significant and often unpredictable costs. The pressure that these companies face in the circumstances is plainly understood, and often leads to settlements that are perceived to not represent a fair value of the patent. Instead, settlement values reflect the risk to the infringing company of avoiding a significant business disruption.

The injunction reform proposals that have been advanced and discussed, however, would not alter the unfair settlement dynamics that have been described. Under the House proposal, injunctions would remain available, but would simply be evaluated under an amorphous and ill-defined standard, rather than standards that have evolved and become settled by more than 100 years of patent jurisprudence.

Any proposal to reform permanent injunctive relief standards will cause significant and practical harm to biotechnology and pharmaceutical companies. The reason is simple - a change which would eliminate any risk from being enjoined following a finding of infringement will fundamentally conflict with the essential business model of the pharmaceutical and biotechnology industries. At the same time, a change which makes an injunction a less certain outcome of a successful effort to enforce the patent will either conflict with the life-sciences industry's business model, or will fail to accomplish what its advocates seek. For this reason, I urge you to avoid pursuing reforms that would call into question the right of a patent owner to obtain permanent injunctive relief once it has proven its patent valid and infringed. Doing so will induce significant political opposition from those sectors of the patent community that depend on patent exclusivity as a central facet of their business. Given the risk that such reforms pose to such companies, it is a certainty that such reform measures will engender significant political opposition, and will prevent successful patent reform.

Proposed Reforms to the Standard for Damages Determinations and Willful Infringement

A second set of reforms seeks to alter how damages are determined in patent infringement settings. These reforms have two elements; namely:

- changes to the statutory language governing determination of damages in certain cases; and
- changes to the standards that define and govern enhanced damages for "willful" infringements.

I believe these reforms, particularly those relating to willful infringement, have substantial merit and can be crafted so as to preserve effective patent protection, yet at the same time, enhance predictability in patent litigation.

The first change, reflected in section 6 of the House bill, would articulate a standard to govern the calculation of damages in instances where an infringing product has multiple features, only one of which is covered by the patent. It would provide that a court, in determining the value of a reasonable royalty, consider the portion of the value or profit of the product that "should be credited to the inventive contribution as distinguished from other features of the combination, the manufacturing process, business risks or significant features or improvements added by the infringer." The change appears designed to codify the standards governing royalty determinations in "combination" inventions that is found in the patent jurisprudence. See, e.g., Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1119-1120 (S.D.N.Y. 1970). The motivation for doing so would be to create a more consistent application of this jurisprudence, and to validate that aspect of the standards that courts use in evaluating damages in these types of infringement scenarios (i.e., combination inventions). Provided that the change merely codifies the rule established in the patent jurisprudence, it should not create significant problems within the patent system.

The other area of damages reform concerns the issue of "willful" infringement. As proposed in the House bill, the willful infringement standard would be recast to more precisely identify the nature of the conduct that amounts to willful infringement. In addition, the statute would place certain restrictions on how and when willful infringement assertions could be made, and would address how opinions of counsel concerning patents are used in willfulness determinations.

In general terms, the proposed standards make useful improvements to the state of the law governing willful infringement.

- The more explicit definitions of the conduct that can be found to constitute willful conduct are generally consistent with what courts have found to be clear examples of the conduct that should be punished through the award of enhanced damages.
- The proposal would permit a party accused of willful infringement to avoid enhanced damages if the infringer could establish that it had a good faith basis for believing the patent to be invalid, unenforceable or that it would not infringe the patent by the conduct in question. While this is an improvement, the statutory language should also make clear that a party that seeks to avoid infringement, such as by modifying its product or taking other steps, can also rely on these efforts to establish that it did not willfully infringe the patent.

- The House bill would clarify that attorney opinions about patents are to enjoy protection from discovery, and that the refusal of a party to waive its attorney client privilege by producing such opinions will not prejudice its position on the issue of willful infringement.
- Finally, the House bill would limit when a patent owner could plead and when a court may address willful infringement assertions. This change will cut down on unnecessary litigation over allegations of willfulness, by requiring a court to first find that there is, in fact, infringement, a necessary predicate to a finding of willful infringement.

The changes proposed in the House bill will help address the main problem with existing jurisprudence on willful infringement. Specifically, parties often claim willful infringement simply as a litigation tactic. The claim then manifests itself in demands for production of opinions of counsel as to the validity or infringement of the patent, and efforts to place into evidence information that is unnecessary and irrelevant to the question of infringement. By incorporating measures that better define what constitutes willful conduct, and how willfulness allegations are to be handled in litigation, the legislation would significantly improve the standards governing this area of damages determinations.

Reforms to Regulate "Continuation" Practice

Another issue that has been raised in Congressional hearings and other fora of public debate on patent reform is the concern over "abusive" continuation practice. Continuation practice refers to the practice of filing additional applications linked to and having the same disclosure as earlier applications. By doing so, an applicant can continue "prosecuting" its applications, and seeking new claims, for an extended period. The proposal appears to be focused on the problem of parties that first present broad claims long after an initial application has been filed, with the intent of capturing the intervening market entry by a competitor who believed that there would not be a patent obstacle.

Under existing PTO practices, biotechnology patent applicants are often subjected to extensive restriction requirements. This means that for each invention that is pursued in a first application, an applicant often must file dozens of additional "divisional" applications to obtain meaningful and sufficient claim coverage. Under existing law (35 U.S.C. 121), those applicants have the right to defer the filing of these additional applications. If the law required the immediate filing of dozens of voluntary divisional applications, it would place unjustified additional expenses and time burdens on biotechnology applicants. This is a particular hardship on small biotechnology companies and universities, which often rely on the services of outside counsel, have limited financial resources, and face uncertain licensing opportunities for their inventions. Further, in many cases, new questions of law or practice arise during the examination of an application. These new standards not only cause applications to undergo a protracted examination process, they also clarify what types of claims a patent applicant may pursue.

The House bill would vest the Director of the PTO with the authority to promulgate regulations that would govern the filing of continuation applications. It is not clear what would constitute appropriate or inappropriate conduct under the House bill. Indeed, the legislation would simply authorize the Director to regulate the practice of filing continuation applications.

To fairly evaluate legislative proposals of this nature, two issues need to be resolved. First, many biotechnology and pharmaceutical patent applicants file continuation applications that supplement the original contents of the earlier filed application. These so-called "continuation-in-part" (CIP) applications often include additional results from experimental testing, and other information generated through additional research on the invention. These applications provide value to the public through the enhanced disclosure of scientific knowledge. As such, whatever measures the Director is instructed to implement should be careful to distinguish CIP applications from ordinary continuation applications. Second, the prosecution of biotechnology patent applications before the PTO is often an arduous, complicated process. In many cases, significant changes to the law have occurred during the time that applications are pending before the PTO. Given the necessity of biotechnology companies to secure meaningful patent protection, the law must ensure a right of biotech applicants to obtain effective patent claims for any inventions disclosed in their applications. With such clarifications, legislation that authorizes the Director to regulate when continuations may be filed so as to avoid abuses from such filings, may prove acceptable.

Post-Grant Opposition Procedures

Legislation to create a cost-effective, vigorous and fair procedure to review the validity of issued patents will significantly improve the patent system. A cost-effective procedure that allows for robust participation by third parties yet is appropriately limited to avoid prejudice and the problems of litigation before a Federal court, would provide immense value for patent owners and the public alike. As the Senate begins its deliberations regarding the creation of a post-grant opposition procedure, it should keep certain fundamental principles in mind.

First, there is no right of a member of the public to retain and enforce an invalid patent. It also is not appropriate to permit entities to use the high cost and complexity of patent litigation to forestall discovery of the invalidity of a patent. Invalid patents can impose an immense and unjustified cost on American businesses, including companies in the biotechnology industry.

Second, a properly designed system must incorporate safeguards to ensure that it will not be abused by third parties.

The challenge is for Congress to create a procedure that provides a rigorous and balanced inquiry into the validity of a patent, and to make that procedure feasible for the PTO to administer. A system that permits a third party to paralyze a patent by initiating an open-ended administrative proceeding would seriously undermine the incentives and purpose of our patent system. Likewise, a proceeding that becomes comparable in complexity, burden and cost to litigation in the Federal courts would yield no benefits.

Finally, a patent review system administered by the PTO must remain focused on those issues that the PTO has special expertise in evaluating, and work within the practical constraints of an administrative proceeding that is designed to be efficient but thorough. In particular, the system should avoid having the PTO evaluate questions of compliance with the "best mode" requirement of 35 U.S.C. §112, or compliance with the duty of disclosure under 37 CFR §1.56. The system should also build on the recognition that the PTO can bring a special technical expertise to independently evaluate scientific and technical questions that bear on patentability. At the same time, the PTO is not well-equipped to manage contentious proceedings that will turn on critical evidentiary questions. As such, I encourage the Congress to incorporate safeguards that take account of these limitations, and to not create a system that the PTO is incapable of effectively managing, or which leads to unjustified costs.

An appropriately structured post-grant review system will enhance public confidence in the patent system, and provide the public with a much needed administrative alternative for resolving questions of patent validity. The recent reports from the Federal Trade Commission (FTC) and the National Academies of Science (NAS) reinforce this conclusion. Each organization recognizes that the PTO has a special expertise in evaluating certain patentability issues, such as anticipation, nonobviousness, enablement, written description and utility and that an administrative patent validity review proceeding can be conducted more rapidly than litigation in a Federal court. They correctly find that the public would significantly benefit from the availability of a procedure that does not present the burden, duration and associated expenses of patent litigation. These organizations also appreciate that any new system should not permit third parties to harass patent owners, or initiate groundless attacks on patents.

Past Congressional efforts to establish a procedure by which the PTO can review the validity of an issued patent have been well-intentioned, but have not produced a procedure that is viable. The first such system adopted by Congress was the "ex parte" reexamination system, enacted in 1982. In the ex parte reexamination system, any person, including the patent owner, may commence a reexamination of any issued patent on the basis of a patent or a printed publication that raises a substantial new question of patentability. See, 35 U.S.C. §302. The ex parte reexamination procedure, like original examination, is a closed procedure - only the patent owner and the PTO participate substantively in the proceeding. As a result, most third parties avoid use of this procedure for commercially significant patents, since it does not afford those third parties a meaningful opportunity to participate in the proceeding.

In 1999, Congress created an enhanced version of reexamination, termed "inter partes" reexamination. The inter partes reexamination procedure does provide more of an opportunity for third parties to participate in the proceeding. However, due to the limitations built into the system - particularly the onerous estoppel conditions -this "enhanced" version of reexamination has fallen short of expectations. The limited number of inter partes reexamination requests that have been commenced -despite the fact that hundreds of thousands of otherwise eligible patents have issued since enactment of the legislation -suggests that the design of this procedure will continue to limit its use by the members of the public.

I believe it is possible to create a viable, cost-effective, and fairly balanced post-grant administrative patent review procedure. The approach set forth in section nine of the House bill is a good starting point, but several important variables need to be revised to make that system acceptable.

- Single Window for Initiating Opposition, and Requirement to Conclude Proceeding within Reasonable Period. A third party should be allowed to initiate a post-grant review proceeding provided it makes a sufficient preliminary showing only within a single fixed period following issuance of the patent. In my view, the optimal period is nine months. To be viable, the post-grant proceeding must be concluded within a reasonable period, namely, 12 to 18 months. The legislation should confirm that this deadline will be respected by the PTO.
- Threshold Showing to Initiate Procedure - An opposition system should require any party wishing to commence a proceeding to provide a cogent and well-supported written showing that establishes at least one claim in the patent is invalid. The statute should require the PTO to make an independent determination that the opposer's showing meets a threshold level of merit that a question exists as to the validity of one or more claims in the patent. If the initial showing is not sufficient, the Office should not commence the proceeding.
- Estoppel. Participation in a post-grant review system must not create any barrier for the participants to later litigate patent validity on issues that were not actually raised and addressed in the post-grant review proceeding before the PTO. Incorporating estoppel provisions that extend past those issues that were actually addressed in the proceeding will likely create the same types of problems that have led to the lack of use of the inter partes reexamination procedure.

- Limited Additional Evidentiary Procedures. A viable post-grant review procedure should permit use of evidentiary procedures that will provide a more rigorous review of issues pertinent to the validity of a patent than are permitted under the current inter partes reexamination authority. However, if all the evidentiary procedures available in litigation before a Federal Court were allowed to be used in a post-grant review procedure, no benefits would be realized from using the PTO-based procedure. As a result, only certain limited additional procedures should be allowed in a post-grant review procedure; namely, the right to cross-examine a witness who offers testimony in the proceeding, and, if the presiding authority finds it appropriate, limited requests for admissions and an opportunity for an oral hearing. Other measures, however, should be expressly prohibited in the law. In particular, parties to a post-grant proceeding should not be subject to document production, or forced to produce fact witnesses for depositions. Such restrictions are appropriate and will not undermine the effectiveness of the procedure.
- Regulate Party Conduct in Opposition Proceedings Under the Standards Used in Court. The post-grant system should impose identical obligations and responsibilities on all parties to an opposition proceeding. This means, in part, that the legislation should include a provision which holds that a patent may not be held unenforceable due to those events that arise during the opposition proceeding. Such a provision should also confirm that if the PTO finds that one party has made a misrepresentation, it should have the authority to take actions to sanction that party appropriately. Where such misrepresentations are discovered after the patent emerges from the proceeding, courts may give due consideration to the actions of the party, but should not be allowed to hold the patent unenforceable.
In the recent public debates, there appears to be a significant amount of public support for creation of an appropriately balanced and fair post-grant opposition procedure. The critical issues to be resolved in the discussions concern certain issues that reflect differences among industry perspectives on the patent system. For example, a procedure that would permit any party accused of infringement to commence an opposition at any time fundamentally conflicts with the business model of many biotechnology companies. Biotechnology companies must be able to count on the security of issued patents, particularly after the company has successfully brought a product to market. As time passes, the necessity of being able to use the full scope of discovery available in civil litigation becomes more important. Given that post-grant procedures will impose strict limits discovery, it is inappropriate to open a "second window" of opportunity, particularly one that is triggered by the assertion of the patent in litigation. Inclusion of such a "second window" in the post-grant procedure, in my opinion, will engender significant political opposition and will create many practical problems for the PTO in their administration of the post-grant authority.
The other area that warrants further consideration is the standards used to commence and conduct opposition proceedings. Legitimate concerns exist as to how detailed a showing must be to justify commencement of an opposition procedure. Similarly, questions exist about how the PTO will manage evaluation of certain types of evidence. Views from various industries differ significantly on these factors. However those factors are set in the legislation or in the PTO regulations that implement the system, they must ensure that the post-grant procedure does not become an opportunity to simply harass patent owners.
Reforms to the Standards Governing Enforceability of Patents
Section five of the House bill proposes to reform the law governing inequitable conduct. In general terms, reform of this doctrine is long overdue, and the changes proposed in the House bill will go far to addressing the problems in the law.
Section 282 provides that a party accused of infringement may raise a defense that the patent is unenforceable. Unenforceability is a defense distinct from invalidity of the patent or from non-infringement. It operates to preclude the patent owner from enforcing a patent that is otherwise meritorious - meaning that the invention claimed in the patent is novel, not obvious, useful, and adequately described. It has evolved over the years from several equitable doctrines, the most dominant of which is the assertion by a defendant that the patent is unenforceable because the patent owner committed a fraud on the PTO in the process of obtaining the patent. From this legitimate foundation, the doctrine of "inequitable conduct" has arisen and flourished to an inappropriate degree.
As several courts have observed, claims of inequitable conduct have become what is justifiably labeled as a "plague" on modern patent litigation. Inequitable conduct is routinely raised in patent cases, and often is based on the flimsiest of assertions. The reason is simple - by pursuing this defense, a patent on an invention that is otherwise meritorious can be nullified by making it impossible to enforce.
The inequitable conduct doctrine, however, has created significant problems for patent applicants and for the PTO during the examination of applications. The most significant problem is that communications between the patent applicant and the patent examiner are now a contorted and restricted dialogue, primarily because of the risk that these communications made honestly and in good faith will be turned into a story of inequitable conduct when the patents are put into litigation in the future. Concerns about creating a foundation for a claim of inequitable conduct may cause applicants to be overly inclusive in citing information to the PTO. This often results in situations where the patent examiner is given an immense amount of information solely for the purpose of foreclosing a claim that the applicant was concealing information from the examiner, thereby imposing unnecessary burdens on the patent

examination process. Moreover, applicants can be put into a "Catch 22" situation in that they can later be accused of "burying" a reference if they cite many references to the PTO to satisfy their Rule 56 obligation as defined by the courts.

Plainly, reforms to this doctrine are necessary. Reforms should be made that provide that a party may not raise an assertion of inequitable conduct in respect of a patent unless at least one claim of the patent were shown to be invalid on the basis of the disputed prior art or information. Such a change would establish a more objective threshold finding of significance for the disputed subject matter and would supplant the existing "materiality" standard. The law should also continue to require the party asserting inequitable conduct to independently establish a specific intent of the applicant to mislead the PTO. Such reforms would change how parties could raise inequitable conduct assertions in litigation, and would reduce the opportunistic uses of such pleadings in litigation.

Reforms to Implement a First Inventor to File System

Sections 2 to 4 of the House bill would make substantial changes to portions of title 35 that govern patent eligibility. In general terms, these reforms reflect changes necessary to implement a "first inventor to file" standard in the U.S. patent system.

The change to a first-inventor-to-file system will create a "best practice" that merges the protections of our current system for inventors with the practical realities of a global patent system. The changes proposed in the House bill incorporate special protections for inventors to secure patent rights, even in instances where they have filed an application after another party that is not an actual inventor. The standards thus protect the interests of small entities and independent inventors, by giving them an avenue to contest applications made by an earlier filer who is not an inventor.

In general terms, the changes proposed in sections 2 to 4 of the House bill are sound and will significantly improve operation of the U.S. patent system. These changes will provide a more objective set of patentability standards, which, in turn, will decrease the uncertainty of patent litigation. The changes also will present a path forward to greater coordination between the major patent offices of the world. They will do so by enabling the PTO to apply a more consistently defined and objective set of prior art standards, which will enable the PTO to rely on the work product of other offices, and vice versa. The changes thus will enable the PTO to expedite the examination of applications that have been previously reviewed in other patent offices, thereby decreasing examination times and increasing quality. I believe these types of reforms will enjoy broad support among the various sectors of the patent user community.

Conclusion

I thank the subcommittee for the opportunity to present my views on the topic of patent reform, and encourage Congress to work with all sectors of the patent community to ensure that the best package of reforms can be pursued and enacted into law.