Testimony of

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April 25, 2005

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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 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.

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Robert A. Armitage has served Senior Vice President and General Counsel for Eli Lilly and Company since January 1, 2003. He joined Lilly in 1999 as Vice President and General Patent Counsel. Prior to joining Lilly, he was a partner in the Washington, D.C. office of Vinson & Elkins LLP (1993-1999). Among other positions, he has served as an adjunct professor of law at George Washington University Law School (1996-2000), a member of the board of directors of Human Genome Sciences, Inc. (1995-1999) and as chief intellectual property counsel for The Upjohn Company (1983 to 1993).

He has served in a variety of leadership positions in the intellectual property bar, including as a president of both the American Intellectual Property Law Association (AIPLA) and the Association of Corporate Patent Counsel (ACPC). His other leadership positions include service as chair of the following organizations: National Council of Intellectual Property Law Associations (NCIPLA), the Fellows of the American Intellectual Property Law Association, the Patent Committee of the Pharmaceutical Research & Manufacturers of America (PhRMA), the Intellectual Property Committee of the National Association of Manufacturers (NAM), and the Intellectual Property Law Section of the State Bar of Michigan.

He as also served as a member of the board of directors of both Intellectual Property Owners (IPO) and the National Inventors Hall of Fame Foundation (NIHFF), and as a member of the Advisory Board for the Patent, Trademark & Copyright Journal of the Bureau of National Affairs, Inc. He is currently serving as a member of the Council for the Intellectual Property Law Section of the American Bar Association (ABA IPL Section) and co-chairs the AIPLA Special Committee on Patent Legislative Strategies.

Mr. Armitage has lectured and written on a wide range of intellectual property subjects and testified before the United States Congress on IP policy issues. He has also testified as an expert in patent law and practice in a substantial number of patent litigation matters.

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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. 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 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:

o 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."

o 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."

o Intellectual Property Owners Association stated that "IPO supports first-inventor-to-file because it is the best system for the U.S."

o 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 inventor 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. 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.

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 though 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.

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. 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 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.

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.

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 is 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 AIPLA-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.