



Answers That Matter.

Statement of
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Before

The United States House of Representatives
Committee on the Judiciary
Subcommittee on the Courts, the Internet, and
Intellectual Property

On

“Patent System Harmonization”

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Chairman Smith, Ranking Member Berman, and Members of the Subcommittee:

Mr. Chairman and Ranking Member Berman, my name is Robert Armitage. I currently serve as Senior Vice President and General Counsel for Eli Lilly and Company, located in Indianapolis, Indiana. Prior to joining Lilly, I was a partner at Vinson & Elkins and engaged in practicing intellectual property law. During the past three decades, I have represented individual inventors, small businesses, universities, and multinational corporations. I have worked with clients seeking to defend and enforce patents, as well as clients engaged in challenging and invalidating patents. I have also been involved with numerous bar and industry trade associations, where I have played an active role in garnering support for patent reforms. It is an honor for me to again appear before this Subcommittee to address the manner in which patent harmonization initiatives are related to the desire for broader patent system reforms.

Patent Reforms Past: Where We Have Been for the Past 40 Years

I last had the opportunity to appear before this Subcommittee to address patent harmonization issues nearly 14 years ago. On April 30, 1992, this Subcommittee and its Senate counterpart held joint hearings on the “Patent System Harmonization Act of 1992.” At that time, I appeared on behalf of the National Association of Manufacturers, as chair of its Intellectual Property Committee. The thrust of the hearing centered on the advisability of moving forward with a first-inventor-to-file system in the United States.

The highlights of my 1992 testimony included the following observations, which I submit are as valid today as they were then:

... The interests of U.S. inventors would be well-served under a first-to-file system. NAM’s support for “first-to-file” derives from the costs, delays, complexity and uncertainties created by existing first-inventor proceedings. A first-to-file rule would greatly reform and simplify U.S. law, while affecting a minuscule number of second-to-file inventors who currently, but often at great expense, prevail in patent interference contests.

A first-to-file system would benefit “small entity” inventors (independent inventors, university inventors and small businesses), who appear most disadvantaged under the multiple burdens of existing U.S. first-inventor practice.

...

Prior user rights represent an important and essential feature of this legislation. These rights are needed to assure that investments in U.S. manufacturing facilities are not compromised by later-filed patents. Without prior user rights, the United States would be at a competitive disadvantage in attracting investment in new manufacturing facilities

relative to other industrialized countries, all of which recognize such rights.

...

Other changes to the U.S. patent system that should be considered by Congress are endorsed by NAM [including] elimination of the “best mode” disclosure requirement, limiting the “on sale” bar to an actual sale of the invention, and restricting the remedy for “inequitable conduct” to denial of pre-judgment damages. As proposed by NAM these changes would profoundly reduce the cost of enforcing patents by severely limiting matters on which discovery would be necessary to assess patent validity.”

Joint Hearing Before the Subcommittee on Patents, Copyrights and Trademarks of the Senate Committee on the Judiciary and the Subcommittee on Intellectual Property and Judicial Administration of the House Committee on the Judiciary, 102nd Congress, Second Session, on S. 2605 and H.R. 4978, April 30, 1992, S.N. J-102-57 (Senate) and S.N. 122 (House), p. 190.

The identified needs for reform in 1992 were grounded on serious concerns over the delays and uncertainties built into the existing first-to-invent system, the expensive “patent interference” system that the United States Patent and Trademark Office must administer to make it work, and its inherent unfairness to the least resourceful inventors. In my 1992 testimony, I observed the following on the issue of fairness:

... To those who would argue that the first inventor system adds fairness to our patent system, NAM would ask, Fairness for whom? Our patent system only rarely determines that the first inventor is someone other than the first-to-file; statistically, needles in a very big haystack of patents granted each year. Even when it does, it does so at such expense and with such delay, that who but the most resourceful inventor can see the process through to a successful end?

Joint Hearing, *supra*, p. 194.

The United States is the only country in the world in which a person can be the first to make an invention and be the first to seek a patent for an invention, but nonetheless forfeit the right to obtain a patent on that invention to someone who much later made the same invention and even later sought a patent on it. Only in the United States is a person who is the first to make an invention, and who becomes the first to seek a patent on it, saddled with the fear – and forced to bear the risk – that some johnny-come-lately inventor may wrestle away the right to patent.

The irony of our current first-to-invent system is how poorly it serves the interest of the first inventor, not how well it does so. The United States suffers with the world’s only patent system that does not guarantee that the first inventor can always secure the right to patent his or her invention. Even worse, recent and exhaustive research has revealed just how unfairly our current first-to-invent system has operated in awarding patents when the issue of “which inventor is the first inventor” is in dispute.

This research has empirically demonstrated that in the “first inventor” determinations, size does matter – and matters decisively. Because the patent interference system depends upon keeping detailed records of invention, having access to corroborators of the inventor’s work, complying with Byzantine procedural requirements of a patent interference, and persisting to the conclusion of this hyper-expensive administrative proceeding, the so-called “small entity” inventors suffer a significant net loss of patents to “large entities” in patent interference contests.

The latest data demonstrate that, had Congress enacted the Patent System Harmonization Act of 1992 in 1992, independent inventors, universities, small businesses, and other not-for-profit entities would have been awarded more patents, and would have saved substantial sums of money that were instead spent on patent interference contests. In short, the small entities would have received more patents, at much less expense, much more quickly, and with greatly reduced uncertainty.

The concerns over the operation of the first-to-invent system, especially its impact on the “small entities” were not new ones in 1992. Indeed, during the past four decades, no one has completed a serious look at reforming the U.S. patent system without reaching the conclusion that preserving the first-to-invent principle makes no conceivable sense – for “small entities” that are disproportionately disadvantaged by this system or for “large entities” that also must bear its costs, delays and uncertainties.

The best way to understand these concerns is through a brief recap of three seminal studies of the U.S. patent system that have taken place during the last forty years. Exactly 40 years ago, on November 17, 1966, the President’s Commission on the Patent System issued its report advocating, among other things, greater patent law harmonization based upon a first-inventor-to-file system. The context of that recommendation is best understood, however, not as a singular push for the “first-inventor-to-file” rule, but as a call for a balanced and comprehensive set of initiatives to improve the U.S. patent laws. The President’s Commission identified the need for achieving six objectives. A strong case can be made that not a single word of the 1966 text needs changing to define a complete 2006 patent reform agenda:

1. To raise the quality and reliability of the U.S. patent.
2. To shorten the period of pendency of a patent application from filing to final disposition by the Patent Office.
3. To accelerate the public disclosure of technological advances.
4. To reduce the expense of obtaining and litigating a patent.
5. To make U.S. patent practice more compatible with that of other major countries, wherever consistent with the objectives of the U.S. patent system.
6. To prepare the patent system to cope with the exploding technology foreseeable in the decades ahead.

Report of the President's Commission on the Patent System, 1966, pp. 3-4.

The 1966 President's Commission was not unmindful of the need for a fair patent system, operating in the public interest and the interests of all inventors. Its rationale for moving away from a first-to-invent system is instructive because the "fairness" rationale that the Commission set out has only grown in vitality over the intervening decades:

In a first to file system, the respective dates of "conception" and "reduction to practice" of the invention, presently of great importance in resolving contested priority for an invention claimed in two or more pending applications or patents, no longer would be considered. Instead, the earliest effective filing date would determine the question of priority. This necessarily follows from the provision that the disclosure in a patent or published complete application shall constitute prior art as of its effective filing date. Interference proceedings thus would be abolished.

Important considerations dictate this departure from our present practice. A first to file system will: encourage prompt disclosure of newly discovered technology; substitute for the delays and expense of interference proceedings a fair and inexpensive means by which an inventor can establish priority; and bring U.S. practice into harmony with that prevailing in almost all other industrial nations.

The Commission believes it is as equitable to grant a patent to the first to file as to the one who wins an interference. Many circumstances may determine the winner in either case. But the first to file is more apt to be the inventor who first appreciated the worth of the invention and promptly acted to make the invention available to the public.

President's Commission, *supra*, pp. 5-6.

A quarter century later, the Secretary of Commerce's Advisory Commission on Patent Reform issued its report on the patent system. The Advisory Commission, like the President's Commission, supported adoption of a first-inventor-to-file system. Again, like the President's Commission, the Advisory Commission saw the advantages of a first-inventor-to-file system in the context of a broader set of reforms to U.S. patent law. Specifically, on the first-inventor-to-file issue itself, the Advisory Commission saw the need to accompany it with contemporaneous reforms to the U.S. patent laws providing for a one-year "grace period" for inventors, permitting a system for simplified or "provisional" filing of patent applications, and affording limited prior user rights to later inventors. Given that these conditions were part of a move to the first-inventor-to-file principle the Advisory Commission's August 1992 report concluded:

The proposed first-to-file system thus would provide a simple and inexpensive means for establishing priority of invention, while at the same time making it easier for all inventors to gain access to the patent system. The new system would reduce the time and expense of obtaining patents

by providing a readily determinable date of priority, and would afford greater certainty in rights for U.S. inventors.

Advisory Commission on Patent Law Reform: Report to the Secretary of Commerce, August 1992, p. 12.

The Advisory Commission also touched on other issues that would advance greater harmonization among patent systems, but with an eye to improving the certainty, transparency and objectivity of the operation of U.S. patent law. This included a recommendation to simplify key parts of the law of patentability:

[T]o eliminate excessive transaction costs, the Commission recommends removing bases for challenging patent validity that do not provide a corresponding public benefit. In particular, the Commission recommends that the best mode requirement of 35 U.S.C. 112 be eliminated, and that the “on sale” bar of 35 U.S.C. 102(b) be restricted to actual completed sales, measured in terms of completed sale plus delivery, rather than mere offers to sell. ...

Advisory Commission, *supra*, p. 14.

Forwarding ahead another dozen years, the National Research Council of the National Academies of Science, following an intensive, multi-year examination of the U.S. patent system, set out a series of recommendations for addressing longstanding concerns over the operation of the U.S. patent system. This multi-year effort engaged some of the Nation’s best and brightest minds.

The final two recommendations of the National Academies were targeted to patent harmonization issues. Just as the two commissions had done, the National Academies proposes a comprehensive and integral reform package, with a particularly important focus on civil justice for patent litigants:

6. Modify or remove the subjective elements of litigation. Among the factors that increase the cost and decrease the predictability of patent infringement litigation are issues unique to U.S. patent jurisprudence that depend on the assessment of a party’s state of mind at the time of the alleged infringement or the time of patent application. These include whether someone “willfully” infringed a patent, whether a patent application included the “best mode” for implementing an invention, and whether an inventor or patent attorney engaged in “inequitable conduct” by intentionally failing to disclose all prior art when applying for a patent. Investigating these questions requires time-consuming, expensive, and ultimately subjective pretrial discovery, a principal source of soaring litigation costs. The committee believes that significantly modifying or eliminating these rules would increase the predictability of patent dispute outcomes without substantially affecting the principles that these aspects of the enforcement system were meant to promote.

7. Reduce redundancies and inconsistencies among national patent systems. The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of results. Differences that need reconciling include application priority (“first-to-invent” versus “first-inventor-to-file”), the grace period for filing an application after publication, the “best mode” requirement of U.S. law, and the U.S. exception to the rule of publication of patent applications after 18 months. This objective should continue to be pursued on a trilateral or even bilateral basis if multilateral negotiations are not progressing.

A Patent System for the 21st Century, National Research Council of the National Academies, June 2004, pp. 11-12

Thus, this short tour of “Patent Reforms Past” demonstrates a remarkable consistency in diagnosis and proposed therapy over four decades. The quotations make the case that those who have taken a deep dive into substantive patent reform have not been able to resurface without advocating reforms that make aspects of U.S. patent law operate more in harmony with patent systems outside the United States.

Perhaps more significantly, however, these “deep-dive” efforts all resulted in recommendations for comprehensive and integrated patent reforms, not just a limited set of harmonizing changes. The patent law is complex, the patent system serves many constituencies with diverse interests, and patent reform typically means seeking out a fair and balanced agenda of changes.

With this background as prelude, I would like to take the opportunity to relate these past patent harmonization and larger patent reform efforts to contemporary reform initiatives, specifically the proposals for patent reform that are being discussed by this Congress, in many corporate board rooms, and among the various other constituencies that are impacted by the patent system. Remarkably, for any participants in the discussions on this topic from 1966 or 1992, there will be no small measure of *déjà vu* from an inspection of the contemporary reform menu – first-inventor-to-file, best mode repeal, expanded prior user rights, inequitable conduct reform, and 18-month publication of all pending applications for patent.

Patent Reforms Present: The Coalition for 21st Century Patent Reform

Lilly is a member of a coalition of companies and organizations working for broadly based reforms to the U.S. patent law. This group has taken the name “Coalition for 21st Century Patent Reform.” Members of the Coalition include many of this country’s most admired and successful corporations: 3M, Caterpillar; Dow; Eastman Kodak; Exxon Mobil; General Electric, which is represented here today by one of its senior executives; Johnson & Johnson; Monsanto; Motorola; Proctor & Gamble; and United Technologies. In addition, Coalition members include the American Intellectual Property Law Association and the Intellectual Property Owners Association, two of this country’s most widely respected voices on IP law issues.

While Lilly is a member of this Coalition, I am here today on behalf of Lilly and not as a representative of the Coalition. That said, I will from time to time reference views of Coalition members that reflect my best understanding of what I believe to be common positions among its members.

Patent Quality and Civil Justice

Individual members of the Coalition have not been shy about exposing the seriousness of the problems facing the U.S. patent system or the very significant reforms that Coalition members are prepared to support in order to address those problems. In brief, patent quality must improve. As a measure of the seriousness of the Coalition's efforts, on September 1 of last year, the Coalition offered a detailed and comprehensive legislative proposal for sweeping reforms to the U.S. patent laws.

Lilly believes that the time has come to end any debate about whether patent quality today is good or bad. How to best characterize the work of the United States Patent and Trademark Office today is beside the point. There is virtually unanimous agreement that no matter how good patent examiners are today at tackling the increasingly complicated job of patent examination, enhancing the effectiveness of the patent system demands improving the quality of today's patent examination significantly. A troubling "patent quality deficit" exists today. It is reflected in—

- The adequacy of the searching resources of the United States Patent and Trademark Office that permit patent examiners to find the most relevant prior art used to assess the novelty and non-obviousness of an invention.
- The technical proficiency of patent examiners to be able to fully comprehend the complexity of technology that is involved in many of the inventions for which patents are sought.
- The availability of sufficient time during the examination process to make the most complete assessment of the invention and its relationship to existing technology.
- The expertise of patent examiners in the legal precedents that must be applied to determine the various questions of law that determine whether the requirements for patentability have been satisfied.

As technology becomes more complicated and diverse, patents are sought with a greater intensity in more fields of endeavor, and preexisting knowledge grows at an ever accelerating pace, the inevitable consequence is an ever-growing quality deficit that bedevils patent owners and patent challengers alike.

The lower the quality of the examination process that leads to an issued patent, the greater the risk for patent owners that their patents cannot be reliably enforced. Unpredictability in enforcement degrades the value of a patent. Facing questionable success in the enforcement of a patent represents an intolerable situation for businesses where high-risk, expensive and long-extended development activities are needed to ready a patented invention for commercial marketing. It is only the expectation of successful patent enforcement that makes such investments possible.

Patent challengers fare no better when patent quality is inadequate. Patent challengers today suffer from a surfeit of questionable patents, some of which should never have issued and others of which have at best questionable validity. The plight of the patent challenger is further compounded today by the fact that there are no adequate mechanisms under which many such patents can be fully and fairly reexamined.

Closing the patent quality deficit would greatly advance civil justice for patent litigants: fewer questionable patents would most assuredly mean much less patent litigation. Both the need to bring litigation to enforce valid patent rights and the need to defend against questionable patents would diminish.

However, the patent quality deficit is but one aspect of broader overall concerns about the operation of the patent system, concerns that, again, are shared equally by patent owners and prospective patent challengers. Many patents are effectively unenforceable because the cost of enforcement exceeds their economic value. Many questionable patents are immune from any effective challenge for precisely the same reason. The integrity of the entire patent system suffers when valid patents cannot be economically enforced and questionable patents cannot have their validity readily and efficiently readdressed. While enhancement of patent quality would be a key civil justice reform for patent litigants, complimentary reforms are urgently needed. Such reforms must be directed to the heart of the cost, complexity, subjectivity, and unpredictability in the adjudication of patent rights.

Coalition members have been consistent supporters of comprehensive action by Congress on these patent quality and broader civil justice issues. The aim of the Coalition efforts has been to advance a fair, balanced, and comprehensive set of reforms that should make the enforcement of valid patents more certain and more efficient and the elimination of invalid patents more prompt and more complete. In its September 2005 proposal, the Coalition advanced no fewer than a dozen major changes to the U.S. patent laws.

Support for Fair, Balanced and Comprehensive Reforms

In brief, the patent quality and related civil justice initiatives endorsed by Coalition members include measures that would:

1. ***Reign in potential abuses in patent venue by mandating transfer in cases where neither plaintiff nor defendant has any substantial connection to the chosen forum.*** Patent litigation is typically fact and witness intensive. “Venue” reform measures should mandate the transfer of venue for patent infringement actions to a more appropriate forum in situations where there is only a minimal relationship to the original forum. This reform should move patent litigation from a venue with no substantial evidence or witnesses to a forum where the parties have more substantial contacts or where substantial evidence or witnesses are to be found.
2. ***Throttle back on the ability of patent owners to seek punitive damages.*** Patent owners routinely allege infringement of patents is willful and seek treble damages. “Willful infringement” reforms must dramatically cut back on the ability to seek such damages and, even if sought, limit the circumstances in which increased damages can be awarded.

3. ***Force courts and patent damages experts to fully consider the issue of “apportionment of damages,” especially for products incorporating numerous innovative features.*** Patent owners often seek damages based upon the entire profit or value in an infringing product, disregarding an infringer’s contributions that are independent of the patented invention, but are responsible for substantial economic value in an infringing product. “Apportionment of damages” reforms should both (a) clearly and plainly codify the court’s obligation to distinguish (from any value arising from a patented invention) the contribution of the infringer through features or improvements it added, manufacturing efficiencies it developed, and/or business risks it undertook to commercialize the infringing product and (b) set out with equal clarity the appropriate bounds for application of the so-called “entire market value” rule.
4. ***Permit the public to provide patent examiners with relevant prior art before the decision is made to grant a patent.*** Patent owners are sometimes unaware of important information that a patent examiner might use to reject an application for patent. “Pre-grant submissions” reform permits any member of the public the opportunity to provide to the patent examiner potentially relevant information on issues of patentability.
5. ***Provide for a post-issuance revocation opportunity for all patents throughout the life of the patent, starting first with a 9-month window for an “all issues” post-grant opposition.*** Patent owners bring infringement actions on patents of questionable validity that have been issued without any opportunity for significant input by members of the public. The Coalition supports reforms that would permit members of the public to seek a post-issuance revocation of any issued patent at any time during the enforceable term of the patent. The Coalition proposal in this regard comes in two parts. The first of the two parts would provide for a “post-grant opposition” that would open a 9-month window after a patent issues during which any member of the public could seek cancellation of a patent based upon any issue of patent invalidity that can be raised in a patent infringement action.
6. ***Expand the “inter partes reexamination” procedure so that it can serve as a “subsequent window” for post-issuance patent revocation of an issued patent.*** As a “subsequent window” for post-issuance revocation, the existing procedures for “inter partes reexamination” should be greatly expanded. Patent owners today are wholly or partially insulated from the “inter partes reexamination” provisions designed to permit the public to challenge questionable patents at any time during a patent’s life. “Reexamination” reforms should open all issued patents to inter partes reexamination and place tight restrictions on any estoppel that might limit a challenger from later attacking the invalidity of a patent. Congress might further consider opening these reexamination proceedings to consider the “adequate disclosure” issues, *i.e.*, “written description” and “enablement,” in all inter partes reexaminations, not just (as today) where the patent owner amends the claims.
7. ***Provide for universal 18-month publication of pending patent applications.*** Patent owners today can keep patent applications secret within the United States Patent and Trademark Office until a patent actually issues, which can be many years after a patent is first sought. “Publication” reform should mandate publication of all pending applications for patent at 18-months from the date the patent is first sought, facilitating both pre-grant submissions of

information to the patent examiner and preparations by an opposer for the filing of a post-grant opposition.

8. ***Remove the “in this country” limitation on the use of prior, non-published knowledge of an invention that can qualify as patent-invalidating “prior art.”*** Patent owners today can seek and enforce patents on technology that has previously been made fully accessible to the public, unless an accused infringer establishes that the technology has been disclosed in a “printed publication” or that it was known from uses, sales, or other activities that took place *in the United States*. In today’s “flat world,” reforms should permit an accused infringer to invalidate such patents based on the technology’s full public accessibility anywhere, including through use or sale *outside the United States*.
9. ***Eliminate the ability of a patent owner to rely on a secret “invention date” to avoid prior art that would otherwise invalidate a patent.*** Patent owners today can negate the effect of “prior art” that otherwise would render a patented invention invalid (as lacking novelty or obvious) by relying on secret activities to establish an earlier “invention date.” This frustrates the ability to study a patent, search for relevant prior art, and make a firm determination that readily available prior art will invalidate the patent. Needed reforms should eliminate the ability to use such “invention dates” to negate such prior art that would otherwise invalidate the patent.
10. ***Expand the right of a prior inventor who commercializes an invention in the United States to continue using the invention, even if someone else subsequently seeks and obtains a patent on that invention.*** Patent owners today can seek and enforce patents on technology that another inventor is ready to place or has already placed into commercial use in the United States. “Prior user rights” reforms afford such inventors, as well as those that they authorize to work their inventions, an expanded defense to infringement that can allow these commercial users (including those who have completed substantial preparations for commercial use) to commence or continue that use without liability to the patent owner.
11. ***Provide inventors an incentive to seek and obtain fully valid patents – and pave the way for increasing the responsibilities on inventors to work closely and cooperatively with patent examiners to achieve this result.*** Patent owners today justifiably resist providing patent examiners with information that would be the most useful for assuring accurate and complete patent examination. They cite a heightened risk of “inequitable conduct” allegations because the most useful types of information that could be offered to a patent examiner multiply the grounds on which it can be later alleged that the inventor misrepresented information in the course of efforts to fully and candidly explain the prior art and its relevance. “Inequitable conduct” reforms must eliminate this anomaly and provide immunity from a patent unenforceability defense based upon “inequitable conduct,” but *only* for inventors that secure fully valid patents. By immunizing valid patents from “inequitable conduct” allegations through such a “valid patent safe harbor,” the enforcement of the “duty of candor and good faith” would be aligned with the policy objective of actually promoting candor and good faith in dealings with patent examiners and set the stage for increasing the responsibilities of inventors in the patent examination process.

12. ***Heighten the transparency of patent validity/invalidity assessments and eliminate subjective standards from such assessments.*** Patent litigants today are typically confronted at the onset of a patent litigation with issues of patent validity and enforceability whose ultimate resolution is very difficult to predict. This non-transparency arises from the discovery-intensive nature of the legal inquiries relating to patent validity issues. The aggregate impact of a set of patent law reforms should strip away the non-transparent elements in the patent law, including the so-called “subjective elements” in patent litigation. A full patent reform package should mean that the validity of a patent can be assessed under objective criteria, by considering only publicly accessible information relating to the patented invention. Successful reform would, therefore, substantially eliminate the need for the extensive discovery of “invention dates,” subjective motivations, contemplations of “best mode,” or secret commercial efforts.

Relationship to the July 26 Chairman’s Substitute to HR 2795

Mr. Chairman, the Coalition’s approach to patent reform should be familiar to you and other members of the Subcommittee. This approach is quite similar to the agenda you first advanced in a Committee Print of April 14 of last year and then later refined in HR 2795, the bill you introduced last June. On July 26 you then tabled a substitute text to HR 2795 that the Coalition has since used as a basis for its efforts.

Allow me to describe the relationship between your July 26 substitute text and the proposals that Coalition members now advocate for patent reform, starting with the first substantive section of the July 26 substitute text, section 3, and continuing through section 9, the last substantive section of the substitute.

First, with respect to the first-inventor-to-file reforms in section 3, the Coalition has lent its full support to the incorporation of this principle into U.S. patent law. The Coalition proposal, however, would establish a more extensive one-year “grace period” than is contained in the July 26 substitute text. This proposal for a more extensive grace period was developed after some extended dialogue with members of the university community. In all other respects, the Coalition is fully aligned with the move to a first-inventor-to-file system as set out in section 3 of the substitute.

Second, section 4 makes additional significant improvements to the U.S. patent system. However, again after some extended consultation with the university community, the Coalition now supports some additional strengthening of the provisions for an inventor’s oath or declaration compared with the provisions in the July 26 substitute. Otherwise, the Coalition is in full support of the extensive improvements to the patent system set out in section 4. This specifically includes the implementation of the recommendation of the National Academies of Sciences to repeal the so-called “best mode” requirement.

Third, the Coalition fully endorses section 5. That section will strengthen and expand the “duty of candor and good faith” through a codification of the duty and more administrative attention to its enforcement. However, section 5 would implement the recommendation of the National Academies to limit the unenforceability defense based upon allegations of “inequitable conduct,” but only where the inventor obtains a fully valid patent. The substitute provides precisely the type of incentive to seek and obtain fully valid patents that, first, will advance the goal of patent quality and, second and equally

importantly, will at last pave the way for the increasing applicant responsibility in the patent examination process.

Fourth, the Coalition supports the intent of section 6 to adopt key civil justice reforms related to both compensatory and punitive damages. On the punitive damages side, the July 26 substitute text hits all the right notes and, again, largely implements the recommendation of the National Academies on this point.

On the issue of compensatory damages, Lilly and other members of the Coalition oppose limiting patent damages through the so-called “prior art subtraction” principle. Using this principle would deny many deserving inventors adequate damages. That said, however, the Coalition supports the intent to assure that the principle of “apportionment of damages” is given full and proper weight in patent damages determinations, especially where a complicated product or process incorporates substantial innovation arising from a multiplicity of patented and unpatented inventions.

While the apportionment issue has been contentious and has not produced a consensus on the statutory amendment needed to best address the issue, Lilly believes that the patent statute should be amended to state that, in awarding damages based upon a reasonable royalty, the factors relevant to such determination should include any apportionment required to assure that the damages awarded do not exceed the economic value contributed to the infringing product or process by the use made of the invention. Such apportionment must account for any economic value attributable to the use of other inventions in the infringing product or process, whether or not patented; other features or improvements added by the infringer; the infringer’s manufacturing processes; and the business risks, other than the risk of potential patent infringement liability that the infringer undertook in commercialization. On the other hand, if a sufficient nexus is established between the demand for the infringing product or process and the infringing use made of the invention, the reasonable royalty may be based upon the entire value of the infringing product or process and may further take account of conveyed and other derivative goods.

Fifth, the Coalition is in substantial agreement with section 7 that provides for a host of patent quality and other civil justice reform improvements, most notably universal 18-month publication of pending patent applications, expanded prior user rights, and new opportunities for post-issuance revocation of a patent. Coalition members support expanding – *in an appropriate manner that is protective of the legitimate interests of inventors in securing “quiet title” in their patents* – the opportunities for post-issuance patent revocation by the United States Patent and Trademark Office that would assure the availability of a review proceeding in the Office at any time during the term of any issued patent, on the request of any member of the public.

The July 26 substitute text, like proposals endorsed by the Coalition supports the ability of any member of the public to seek post-issuance revocation of any issued patent at any time during its term through two alternative mechanisms: an “all issues” post-grant opposition that must be sought in the 9-month window after a patent issues and an expanded “most issues” inter partes reexamination opportunity that affords a “subsequent window” for revoking a patent after the 9-month window has closed. The “subsequent window” would extend time-wise throughout the remaining 20-year term of any issued patent.

Lilly is concerned, however, that the new (and, thus, untested) post-grant opposition procedure not be expanded beyond the 9-month window. All of the provisions for post-grant opposition are tuned to affording full and fair opportunity to oppose a patent during the 9-month window after the patent has issued.

Recently, the Patents Depend on Quality Act of 2006 or the “PDQ Act,” numbered HR 5096, was introduced. HR 5096 proposes just such a “subsequent window” for post-grant opposition. Lilly, like other Coalition members, opposes use of the post-grant opposition procedure as a “subsequent window” for post-issuance revocation of a patent. That said, we do support the availability of an expanded inter partes reexamination procedure to serve the purpose of effective post-issuance review.

As proposed in the July 26 substitute text, inter partes reexamination would be open to all significant issues of patent validity, with two notable exceptions. Patent-invalidating prior art that is in the form of the mere knowledge or use of an invention, that is the unpublished knowledge, would not be considered in the expanded inter partes reexamination. Second, unless the claims of the patent are amended, the issues of adequate disclosure in the patent to justify their validity and the related “definiteness” requirement cannot be considered. These are the so-called “section 112” issues of patent validity.

Within the past month, however, the Intellectual Property Law Section of the American Bar Association has reaffirmed the Section’s support for expanding inter partes reexamination to include precisely such section 112 issues for never-amended claims in the patent. While the Coalition has not taken a position on the inclusion of section 112 issues for never-amended claims, it is an idea that could merit further discussion.

As between the many changes to a post-grant opposition procedure that would be needed for it to be a fair and balanced procedure if used throughout the life of a patent – and the expansion of the availability of inter partes reexamination (which is already a life-of-the-patent opportunity for post-issuance revocation of a patent) – the latter vehicle would appear to be the vastly more promising option for reaching a broadly based consensus on how to address questionable patents once issued.

Sixth, the provision in section 8 of the substitute text would provide for expanded public input into the patent examination process by permitting pre-grant submissions of information. The Coalition supports this provision, especially in light of the expanded post-issuance opportunities for members of the public to seek revocation of a patent once issued. This new provision should have the effect of reducing the number of patents that will be opposed because it will permit inventors and patent examiners to address and resolve issues before the patent issues with questionable or invalid claims.

Seventh, the final substantive provision of the July 26 substitute text, found in section 9, contains a provision addressing potential venue abuses. HR 5096 contains an alternative provision that would mandate transfer of venue in certain situations. The Coalition agrees that the issue of potential venue abuses should be addressed by legislation, at least in the context of a full, fair, balanced and complete effort at patent reform. The Coalition supports a transfer of venue provision as a means for doing so, similar to that in HR 5096.

The Imperative to Reject Proposals for Unwise Reforms

Finally, but by no means least in terms of importance, the July 26 substitute text is notable from the vantage point of Lilly and other Coalition members because of what it does not contain. It contains no provision that would change the current law under which, as a general rule, the courts will enjoin ongoing infringement of a valid patent once a final judicial determination has been made that the patent meets all the legal requirements for validity and has been infringed. In this regard, the substitute text differs from HR 5096, which contains precisely a provision on the standard to be applied for permanent injunctions.

The HR 5096 provision on injunctions is both unwise and unnecessary. The comprehensive reforms supported by the Coalition should address critical aspects of the patent quality deficit and result in meaningful civil justice reforms that benefit patent challengers. The reforms will diminish the number and nature of questionable patents and will expand the means for quickly correcting any patents mistakenly issued by the United States Patent and Trademark Office. The impact of these measures will moot any reasoned justification for limiting the right of the inventor to stop ongoing infringement once a patent has been finally adjudicated as valid and infringed. Where a patented invention provides truly innovative technology that an infringer cannot avoid by designing around or creating an alternative innovation, the economic value of the inventor's patented innovation should be measured by the inventor's assured ability to exclude others, absent extraordinary circumstances.

Patent quality and related civil justice reforms should, thus, eliminate the specter of putting someone out of business based upon alleged infringement of a questionable patent that cannot be effectively attacked. Where the expanded opportunities for an accused infringer to mount full and complete challenge to a patent have failed and the patent in question that has been thusly shown to meet the rigorous validity requirements that Congress has imposed – that is, the patented invention that is shown to be unquestionably new, non-obvious, fully described, completely enabled, and defined with definiteness – fairness to the patent property owner should mean stopping the ongoing infringement of the patent.

On the question of the wisdom of abolishing the general rule that ongoing infringement of a valid patent should be enjoined, Congress should be mindful that the world is watching. After 216 years of a patent law based upon an exclusionary right, Congress would be creating a regrettable global precedent if it rejects the general rule that a final adjudication of validity and infringement of a patent should lead to enjoining its ongoing infringement. Under such a precedent, the United States can expect that many other countries will look to changing their own IP laws to reflect any diminished standard of protection afforded in the United States. If a provision is TRIPs-compliant when written into the U.S. IP laws, that provision will be TRIPs-compliant when adopted elsewhere. It is unimaginable that such a U.S.-originated provision of law could be successfully attacked by any U.S.-based interest when it appears in foreign IP laws.

If the patent and copyright laws of a country were to mandate, as HR 5096 would provide, that no injunction can issue until the court considers “the fairness of the remedy in light of all the facts and the relevant interest of the parties associated with invention,” what types of “relevant interest” of an infringer will come into play and what limitation will exist on the “facts” that a court must take account? Perhaps the interest of the infringer is in offering the public cheaper generic drugs and one of the “facts”

is that the generic drug will be more affordable for more potential patients. Perhaps the interest of the infringer is in offering the public a cheaper computer operating system that has a more secure web browser embedded into it and one of the “facts” in that case is that the public would benefit from a computer system less susceptible to attack from worms and viruses. In both cases, absent the right to enjoin patent and copyright infringement in a predictable manner, who will be investing in the next AIDS medicine or Windows operating system?

Moving Proposals Into Legislation

Let me offer a few concluding remarks on “Patent Reform Present.” One of the disappointments on the part of at least some members of the Coalition is that their early support for fair, balanced and comprehensive reform measures, patterned largely on the July 26 substitute text, has not led to a broader consensus on the content of reforms that are both needed and wise. As one member of the Coalition, Lilly is committed to continue the efforts to find common ground for such reforms.

The problems noted in 1966 by the President’s Commission were not significantly different from the problems that the Advisory Commission sought to address in 1992. The conclusions from the 1966 and 1992 efforts remarkably align with the recommendations that the National Academies announced two years ago, following an intensive four-year study. With four decades of consonant analyses of what must be done to improve the operation the patent laws, Lilly urges that the 109th Congress *just do it*: proceed to enactment of a fair, balanced and comprehensive reform package, while resisting efforts to enact unwise reforms.

Patent Reform Future: Set the Stage for Reforms Focused on USPTO Operations

In addition to its focus on civil justice for patent litigants, the 1966 President’s Commission focused on ultimate keys to an optimally functioning patent system – growing the quality and reliability of issuing patents, reducing the duration of the patent examination process, and, above all, better preparing the patent system to “cope with the exploding technology foreseeable in the decades ahead.” The reforms in the July 26 substitute text and the Coalition proposals will both advance these objectives and can set the stage for further reform.

Perhaps not surprisingly, however, many commentators have taken the “glass half empty” view of ongoing congressional activities. Some critics express undisguised disappointment that proposed reforms are incomplete, if not unworthy, because they fail to decisively address the Office’s role in patent quality, reliability, and pendency. Lilly disagrees. The reform “glass” will not only be half-filled after enacting the currently proposed reforms, but filling the bottom half of the glass is self-evidently the necessary first step to getting the top half filled.

Looking to the next generation of patent reform, allow me to suggest two topics that I firmly believe are needed to fill the top half of the glass. The first topic is *governance* of the United States Patent and Trademark Office. The second topic is redefining the *patent examination paradigm* for the information age.

On the first topic, many have called for the United States Patent and Trademark Office to be chartered as an independent agency, with greater flexibility in conducting and financing its operations,

and with mechanisms that assure higher standards of oversight and accountability. Congress has from time to time grappled with this issue; its pros and cons ought to be reconsidered as part of any set of next-generation reforms.

The issue of how best to manage the operations of the United States Patent and Trademark Office is not new. Fourteen years ago, in Senate testimony on behalf of the American Intellectual Property Law Association, I offered the following perspective on the importance of restructuring the Office as an independent agency, with financing reforms coupled with appropriate oversight and accountability mechanisms:

[A]n effective PTO requires that fundamental change be made in the way the PTO is managed. We believe that the PTO needs to be made an independent Government corporation. We believe that the PTO needs oversight by a private sector user committee, and we believe the PTO can't be managed with the financial flexibility it needs without a borrowing authority.

We have come to these conclusions after a wide-ranging survey of our membership. We see in recent years not improvements in quality [of patent examination] but a consistent pattern of quality being decreased.

When we survey our membership, we find the following things. We find the examining corps itself on the patent side complains of inadequate training and supervision. We see the effects of inadequate time available to examine patent applications. We see that search files in the Patent Office have, if anything, declined in quality We also see quality being compromised because of rigid production quotas and pendency goals. We also see examiners complaining of lack of training [on] substantive patent law principles.

In the end, we see that the Patent Office -- at least in our survey tools -- seems to have lower morale and less motivation than 5 or even 10 years ago.

We ask that the PTO be made an independent Government corporation because we believe it needs strong executive leadership in the form of a Commissioner who would be appointed for a fixed term, and ... would have real management responsibilities akin to what a CEO in a private company might have.

...

Finally, we would urge that Congress not apply a Band-Aid approach to PTO problems. We need to reform the patent system: the patent law and the Patent Office. A harmonized, simplified and reformed patent law and an independent, accountable and reformed Patent Office

are absolutely essential in our view to putting the PTO in the forefront among major patent systems of the industrialized world.

Hearing Before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, United States Senate, 102nd Congress, Second Session, on Activities of the Patent and Trademark Office (PTO), May 12, 1992, S.N. J-102-65, pp. 243-244

What has changed in the past 14 years in this analysis? If anything, the needs for a more effective United States Patent and Trademark Office have only become more acute. One cogent analysis of the current situation – an analysis that I believe ought to guide the 21st century governance of the United States Patent and Trademark Office – appears in the response of the Intellectual Property Law Section of the American Bar Association to the report of the National Academies. The IPL Section analysis is available on its website (See http://www.abanet.org/intelprop/reports/NAS_Report.pdf, Response to NAS Report). The Section outlines a four-point governance agenda for enhancing the capabilities of the Office:

1. Mandate the Office undertake a set of five-year strategic, operational, and financing plans.
2. Strengthen the existing Congressional oversight of the Office by mandating a new role for the Patent Public Advisory Committee in the five-year planning processes.
3. Establish new accountability measures through new metrics targeted to accuracy, promptness, and efficiency of the Office.
4. Address adequate and sustained financing for the Office in the context of the new planning, oversight and accountability mechanisms.

ABA IPL Section Response to NAS Report, p. 7.

The IPL Section's reaffirmation of the 1992 AIPLA recommendations merits careful consideration. Without the resources and accountability that will come from governance reforms, it is unlikely that the persistent concerns of the past 40 years over a patent quality deficit will be fully resolved.

On the second topic, the 1966 prediction of the President's Commission that the Office would be required to react and adapt to "exploding technology" has been more than fulfilled. Today, there is not a computer store in any shopping mall in the country that does not house vastly more computing power than existed in the entire world in 1966.

The emergence of the "information age" should cause a fundamental rethinking of the role of the patent examiner and the patent examiner's relationship with patent applicants. These roles and relationships, developed in the 19th century, have remained much the same since.

When the President's Commission made its recommendations, a person attempting to determine whether an invention might be patentable or not, often needed physical access to a library collection of issued patents and other publications, classified to facilitate its manual searching, that was maintained for this purpose by the United States Patent and Trademark Office. In those pre-information age days, trained patent examiners spent much of their professional careers classifying issued patents to be added to this library. Patent examiners and professional patent searchers would become expert at the contents of these patent searching libraries. The paper-based search facilities that were maintained by the Office formed the principal source for finding the "prior art" that could determine whether a patent on an invention could validly be issued.

Patent applications themselves were simpler to understand, simplifying the process of searching prior art to determine if an invention was truly new and non-obvious. Indeed, stepping back to the days when the role of the patent examiner was first defined, many patent applications were generally understood through pictures, drawings of the purported invention, or, if need be, physical models of the invention.

Those visual tools sufficed because many inventions were simple, mechanical contrivances. With a picture or model being worth the proverbial thousand words, the patent application would be augmented by a terse written description, spanning at most a few pages, to establish that the invention and could be carried into practice.

While examining patent applications based on pictures, models, and a few sheets of paper remained retained viability for decades, that viability has progressively declined throughout most the 20th century. Clearly, by the time of the 1966 President's Commission, it was clear that "exploding technology" was placing the patent examination paradigm of under significant stress. Today, that stress is manifest through remarkably changed circumstances:

- Patent searching to find the "prior art" needed to determine if an invention is validly patentable no longer depends upon physical access to the Office's Search Room. Indeed, the contents of that Search Room no longer define the starting point, much less a principal source, for the prior art that will define the patentability for many types of inventions in many technology fields. The quantity of technical information in the public domain and the various electronic technologies needed to access that information now suggest that the model of relying principally on the patent examiner for searching to identify the scope and content of the prior art be rethought.
- Understanding today's complex technologies and their relevance to a patented invention can no longer be gained from inspection of a patent model or even a page or two of simple patent drawings. Patent applications in some fields of technology today are complicated disclosures of complex systems to which subtle improvements have been made or highly intricate manipulations have been incorporated. In many technologies, a 21st century patent application consists of dozens, sometimes hundreds of pages of verbiage whose import may be fully digested only by experts practicing in a narrow field – and, even then, only after careful and extended study. Today, for such patents, attempting to fully comprehend the import of the invention is a formidable intellectual challenge – and one that was unknown when the job of the patent examiner was first created.

- The quantity and intensity of patenting in many areas of technology has grown enormously. The sheer volume of work, whether measured in terms of numbers of patent applications filed, pages of patent disclosures to be comprehended, or numbers of claims presented for examination has increased by orders of magnitude since the examination paradigm in the United States Patent and Trademark Office was first established. Whereas once a patent office could operate with dozens to hundreds of skilled patent examiners, the work of patent examiners requires hiring more than a thousand new patent examiners each year for the foreseeable future just to prevent the current system from imploding. The quantity and intensity of patenting today offers no prospect of scaling the current model of patent examination to a level where the skills, experience and time available for accurately and completely examination patent applications could be achieved in a timely manner.
- The advance of technology has become vastly more rapid. For many patentable discoveries, the typical period needed for patent examination today may long exceed the economic lifespan of the patented innovation. Granting the right to exclude others only after the ability to do so has become economically meaningless makes no sense whatsoever to an inventor. More rapidly advancing technological innovation juxtaposed against a more slowly moving patent examination process also spells disaster for the public. Anyone seeking to implement a new technology needs to know what freedom of action might exist and what embodiments of a new product might be found to infringe patents of others. Where patents remain pending and the ultimate scope of the patent right remains unsettled, the patent system may discourage rather than encourage investments in innovation.

These changed circumstances, among a host of others, suggest that new principles ought to govern any 21st century paradigm for patent examination. Such new principles should redefine the respective roles for the patent examiner, the patent applicant and the public. The needed reforms will most certainly result in *increased applicant responsibility* and *increased examiner accountability*. To enhance the quality and reliability of patent examination, the patent examiner must become more accountable for more fully and explicitly setting out in the public record the basis for patentability of the invention and the patent applicant must play a more affirmative and complete role as the examiner's guide.

Increased applicant responsibility and increased examiner accountability mean redefining respective roles: Who should bear what responsibilities for identification of prior art, for understanding its relevance and significance, for elucidating the relevant relationships between the prior art and the invention, and for assessing the basis on which the patentability criteria are met.

As noted earlier, in his Senate testimony on April 25 of last year, Director Dudas urged that “increased applicant responsibility” be incorporated into the patent examination process. In the year since, the Office has published proposed rules that, in some situations, would dramatically increase such responsibilities on patent applicants.

Whatever the merits of the recent efforts by the Office on issues of applicant responsibility, such efforts have been and will continue to be misguided, if not entirely counterproductive, unless and until Congress enacts the Coalition-supported reforms in the July 26 substitute text that would create the “valid patent safe harbor” from “inequitable conduct” allegations. Indeed, the complete failure of the

Administration to support the Office's efforts by championing the "inequitable conduct" reforms in the July 26 substitute text is all but inexplicable.

Assuming that such reforms are accomplished, Congress should work with the Office and with patent applicant constituencies on the issue of a new patent examination paradigm that – in a fair and balanced fashioned – works to increase both applicant responsibility and examiner accountability.

Conclusions

The time is ripe for enactment of collection of major patent system reforms, one desirable impact of which will be greater patent law harmonization. The Coalition for 21st Century Patent Reform has compiled and is seeking enactment of such reforms. They address a patent quality deficit and otherwise advance the cause of civil justice for patent litigants.

Lilly, as a Coalition member, believes that the burden to demonstrate the wisdom of these reforms has been met. Four decades of study of what is needed to make the patent system work better has produced consistent conclusions that reforms now supported by the Coalition are wise and responsive to the root causes of today's patent quality deficit.

Calls for the delay, division or defeat of these reforms should not be heeded. The burden of persuasion should now fall heavily on those who would obstruct these efforts. Nay-sayers should be put to the task of demonstrating how this fair, balanced and comprehensive effort to address the patent quality deficit and advance civil justice in patent litigation ought not to proceed in its current form.

Finally, as we think through the implications of prompt action by Congress on these patent reforms, the April 25, 2005 Senate testimony of Director Dudas appears to us to require particular reflection. Congress will need to make further changes in the patent law to make the United States Patent and Trademark Office's work more reliable and more prompt. Perhaps the greatest collateral benefit to the patent system from success of the current reform efforts will be laying the essential groundwork for future reforms – first, in United States Patent and Trademark Office governance and, second, in the century-old paradigm for patent examination.

We would encourage, therefore, that this Congress complete the reform process that this Subcommittee began last April so that the next Congress can begin the work of crafting a next generation of needed patent reforms.

April 27, 2006
Indianapolis, Indiana