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THE CONUNDRUM CONFRONTING CONGRESS: THE PATENT SYSTEM MUST BE LEFT UNTOUCHED WHILE BEING RADICALLY REFORMED

ROBERT A. ARMITAGE

ABSTRACT

Patent systems reforms have been recommended by a variety of interests, including the Federal Trade Commission and the National Academies of Science and the private sector. Although calls for radical reforms have undeniable merit, the effectiveness of the existing patent system as an incentive to investment in innovation must be left untouched in the reform process. Unwise reforms include awarding patent injunctions only sparingly and limiting patent damages to nominal amounts for inventions relating to patentable combinations made of existing components. There are, however, "three pillars" that should guide reform: (1) introduce full transparency and objectiveness into the tests for determining patent validity; (2) create comprehensive post-issuance patent revocation procedures; and (3) establish incentives for inventors to obtain fully valid patents by eliminating the "inequitable conduct" defense for such valid patents. Further, the current nineteenth-century patent examining paradigm should be changed to reflect the twenty-first century realities. The new paradigm should demand increased patent applicant responsibility and increased patent examiner accountability.

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THE CONUNDRUM CONFRONTING CONGRESS: THE PATENT SYSTEM MUST BE LEFT UNTOUCHED WHILE BEING RADICALLY REFORMED

ROBERT A. ARMITAGE*

INTRODUCTION

It is a singular honor to give a lecture in honor of Howard Markey. As I speak here today, the future of the patent system is the subject of discussions involving CEOs of major companies, university presidents, and distinguished members of Congress. These discussions reflect the growing importance of the patent system to the country's economy. The importance of today's patent system traces back to Howard Markey and the transformation of the patent law that he was able to guide as the first chief judge of the Federal Circuit. For someone who entered the patent profession before the creation of the Federal Circuit, the transformation has been career-changing.¹ As just one measure of this profound change, almost every major law firm in the country today has a thriving patent practice; before Judge Markey's work in remolding of the patent laws, almost none did.

The theme of patent law transformation that began over two decades ago with the birth of the Federal Circuit forms a very useful predicate for today's topic on patent reform. What motivates CEOs, university presidents, and members of Congress to engage themselves in discussions of the patent system are calls for another reformation of the patent law. If these calls for reform are heeded by Congress, the changes to patent law and practice that would result could prove much more breathtaking in their reach than the changes wrought by the Markey-led Federal Circuit.²

Calls for patent reforms are appearing today in leading newspapers and magazines. Commentators have used the editorial pages of these publications to suggest that today's patent law works erratically at best, sometimes producing irrational, unfair and unacceptable results. Concerns are expressed that Congress needs to act to retool a system that is now granting seemingly silly patents on things like crust-free peanut butter sandwiches or the act of making a single click of a

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¹ See, e.g., Howard T. Markey, Chief Judge U.S. Court of Customs and Patent Appeals, Needed: A Judicial Welcome for Technology – Star Wars or Stare Decisis?, Address delivered to the Judicial Conference of the Sixth Circuit (May 11, 1978), *in* 79 F.R.D. 209.

² See, e.g., The Patent System: Today and Tomorrow: Hearing Before the S. Judiciary Comm. on Intellectual Property, 109th Cong. (2005) (testimony of the Honorable Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office), available at http://www.uspto.gov/web/offices/com/speeches/2005apr21.pdf: see also Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

computer mouse to make an online purchase.³ From the vantage point of some elements in the media, there is much that appears to be wrong with our patent laws - and much to be fixed.

Against this outcry for reforms, allow me to begin by playing the role of contrarian. I suspect it is the same type of role that Howard Markey himself would seek to play if he were here today. How would a contrarian view the calls for reform? In a few words, it would be with great caution. The contrarian would note that before anyone should conclude that the patent system is broken, account should be taken of the undeniable reality that much is right with today's patent laws and with how they operate. Indeed, in macroeconomic terms, a strong case can be made that today's patent system has never operated with greater effectiveness.

Over the past two decades, the patent system has been responsible for a vast supply of venture capital being placed at the feet of innovators. The promise of patent exclusivity – and the riches that may bring – has made investors willing to place huge bets on technology-based start-up enterprises.⁴

Since the enactment of the Bayh-Dole Act,⁵ universities have become engaged – to an unprecedented degree – in the acquisition of patents and in the technology transfer to private enterprise that those patents facilitate. Literally hundreds of universities that formerly had no stake in the U.S. patent system are now using patents licensed to the private sector to transform nascent technologies into tomorrow's technological wonders.⁶

Much commerce exists today in patents themselves.⁷ Private enterprises now exist solely for the purpose of buying and selling rights to patented technology. Commerce in rights to innovation appears to be thriving as never before.

The promise of exclusivity under the patent system has spawned entire new industries that did not exist two decades ago.⁸ From my own parochial viewpoint, perhaps the most incredible achievement of today's patent system lies in the manner in which it has fostered and sustained the biotechnology revolution. The last several decades have been an era of relentless innovation in the life sciences. Patents permitted investments in commercializing amazing new medicines that have saved lives and restored health to countless millions of citizens.

Pharmaceutical and biotechnology companies must expend between one to two billion dollars over the course of about a dozen years to bring a single new innovative medicine to market. Once on the market, seven out of ten times, a new medicine will

³See, e.g., Patti Waldmeir, Get It Now from eBay, Hostage to the Patent Trolls; Intellectual Property: The Auction Site Follows BlackBerry into Court in an American Battle over the Ownership of Ideas, FINANCIAL TIMES (London), Mar. 16, 2006, at Comment and Analysis 15 (discussing the high profile BlackBerry and eBay cases).

⁴ See, e.g., The Patent System: Today and Tomorrow: *Hearing Before the S. Judiciary Comm. on Intellectual Property*, 109th Cong. (2005) (testimony of the Honorable Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office), *available at* http://www.uspto.gov/web/offices/com/speeches/2005apr21.pdf.

⁵ 35 U.S.C. §§ 200–212 (2000); see also 37 C.F.R. § 401 (2006).

⁶ Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*, Sept. 1999, http://www.ucop.edu/ott/bayh.html.

⁷ Cornell University Center for Technology, Enterprise, and Commercialization, *Bayh-Dole Act*, http://www.cctec.cornell.edu/bayh-dole.html.

⁸ Id.

not pay back the cost of its research.⁹ How do pharmaceutical companies sustain themselves given such a risk-laden business model? Today, that sustenance comes almost completely from an effective patent law, one that actually operates to deliver exclusive rights for the biotechnology and pharmaceutical industry inventors.

Today's patent system is not broken, not in crisis, and not in need of radical surgery in order to meet many of the essential expectations of innovators in the life sciences. If the patent system is left untouched, many in the biotechnology and pharmaceutical industries can persuasively argue that the patent system will continue to work for them, and for their partners in universities, to create an endless treasure drove of innovative medicines. Indeed, many leaders of the pharmaceutical and biotechnology industries would contend that the sky is the limit for improving human life and human well-being if we just have the sense to leave our patent system untouched. The patent-dependent success of these industries forms the best case for leaving the existing patent law untouched and thereby avoiding the risk that unwise reform would kill the patent system's effectiveness as its innovation engine.

Of course if all I that had to say today was that an overwhelming case can be made to leave the patent system untouched, it would not be much of a lecture. It also would not be the whole of the truth about the patent system. Allow me if you will, to express what I believe to be the fuller truth of the matter. If the sky is the limit for some patent system users, it is also an equal truth that the sky is falling for others. In brief, these are the Dickensonian best of times and worst of times for the country's patent system.

We should reflect for a moment on the "patent system run amuck" horror stories that we have all read in the media. The patent system has a serious problem if in the minds of opinion leaders in this country it *appears* to have a serious problem. A strong patent system will not endure if conventional wisdom is that it is troubled and troubling. More "crustless peanut butter sandwich" stories have and will shape the public's impression about the patent system and the seriousness of its value to innovation. The questioning of our patent laws by the media will build momentum for changing the U.S. patent law, perhaps in unwise ways. It would be a fair bet that the impact on decision makers has already reached our Supreme Court justices. They are now voting to hear an unprecedented number of patent cases.¹⁰ The cases they are taking go to issues at the heart of the patent right.

We also know that some senior executives in the information technology and financial services industries are clamoring for patent reforms. Some in these industries have made loud and persisting cries for the most radical of reforms to our patent laws.¹¹ Indeed, they sometimes speak in dire terms about the impact of maintaining the status quo. Some in these industries have said that if we cannot

⁹ Neal Masia, The Cost of Developing a New Drug, U.S. DEPARTMENT OF STATE (Jan. 2006), http://usinfo.state.gov/products/pubs/intelprp/cost.htm ("At current levels of reimbursement, economists estimate that only about 30 percent of new medicines actually earn enough revenue during their patented product lifecycle to cover the average upfront cost of development.").

¹⁰ Brandon L. Bartels, *Heterogeneity In Supreme Court Decision-Making: How Case-Level Factors* Shape Preference-Based Behavior, http://psweb.sbs.ohiostate.edu/grads/bartels/research/heterogeneity.pdf.

¹¹ Sarah Lai Stirland, Trolling for Patents, THE SEATTLE TIMES, Nov. 14, 2005, http://seattletimes.nwsource.com/html/businesstechnology/2002622393_patent14.html.

reform our patent laws, the sky is not simply falling, but it *will fall* on some high-technology U.S. enterprises.¹²

But, which is it? Should we look to a limitless sky by simply having the wisdom to leave the patent system untouched, or are we standing under a falling or fallen sky that only radical reforms can repair? With the stark dichotomy between the limitless sky and the falling or fallen sky, it should surprise no one that when patent lobbyists visit Capitol Hill, they inevitably leave our legislators and their staffs perplexed. Congressional leaders can only scratch their heads at the disparate views on the patent system that they are hearing.¹³

This country's most innovative, and therefore most IP-dependent, industries sometimes appear hopelessly divided. They are lobbying Congress with viewpoints on the patent system's operation that often appear irreconcilable. This division is almost unprecedented. When Congress hears from this country's preeminent technology-creating industries, irrespective of industry sector, they typically come to Capitol Hill with highly convergent interests and consonant voices on a wide range of policy issues. The discordant messages on the patent system proclaim on the one hand that *urgent reform is needed to fix a broken patent system*, but then other industry voices contend, on the other hand, that *if any reform is needed at all, it must be reform that leaves the patent system entirely untouched*.

How can this discord exist among IP-dependent enterprises for which effective IP protection is the legal bulwark keeping pirates and free-loading copycats at bay? This question itself is remarkable. If we were to take away this country's IP systems, the effects would be devastating in innovation-dependent enterprises, regardless of industry sector. Destroy IP rights or their effective enforcement and there would be no one remaining in the Biotechnology Industry Organization or the Business Software Alliance, two of the leading industry groups that appear at times to have members sitting on the most opposite sides of the current discord.¹⁴

Congress is attempting to unravel the riddle of these rival views on patent reform. Several congressional hearings have been held thus far in the 109th Congress. More hearings over the next couple months appear to be in the offing.¹⁵ One massive bill to reform the patent laws has been dropped in the House of Representatives. The leadership of the IP subcommittee in the U.S. Senate appears

¹² Bruce D. Radin, *Litigating Challenges To Business Methods/E-Commerce Patents: Lessons Learned from* Amazon.com v. Barnesandnoble.com, Apr. 17, 2000, http://www.morganfinnegan.com/news/articles_publications/0072.

¹³ ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 20–21 (Princeton Univ. Press 2004).

¹⁴ See, e.g., Miyako Okada-Takagi, Japan / US Comparisons of Biotechnology Patents, 6 EUBIOS J. ASIAN & INT'L BIOETHICS 166–68 (1996), available at http://www.csu.edu.au/learning/eubios/EJ66/EJ66M.html.

¹⁵ See Oversight Hearing on "Patent Harmonization": Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 109th Cong. (Apr. 27, 2006) (statement of Rep. Smith, Chairman, H. Subcomm. on Courts, the Internet, and Intellectual Property) ("Today the subcommittee conducts its sixth hearing in the 109th Congress on patent reform."), available at http://judiciary.house.gov/OverSight.aspx?ID=235, http://boss.streamos.com/real/hjudiciary/courts/042706.smi.

to be in the process of putting together legislation that would address issues of patent reform. 16

With all this, which issues stand at the heart of the current discord? From a pharmaceutical or biotechnology industry vantage point, that question has a simple answer: remedies. Some in the pharmaceutical and biotechnology industries believe that they are engaged in a life-and-death struggle over the question of what a valid and infringed patent should be worth. These biotechnology and pharmaceutical industry interests believe that they are confronting extremists, some of whom reside in the information technology industry sector, who want to fix the patent system by eviscerating the prospect of obtaining effective remedies under valid and infringed patents. They believe themselves to be confronted by an adversary whose goal is either to deny injunctions that today reliably stop ongoing infringement of valid pharmaceutical patents or to change to the existing principles on how damages are apportioned to assure reasonable royalties are set at a level that is adequate to compensate for infringement of a valid patent.¹⁷

On the first point, the extreme elements among the IT-industry reformers are seen by some in the pharmaceutical and biotechnology industries as advocating for more widespread judicial licensing of patents. In other words, reform means providing the courts broader discretion to say to an adjudicated infringer of a valid patent who wants to remain in the business of infringing the patent, "You have lost your challenge to the patent, but you get to keep on infringing anyway!"

On the damages point, these same pharmaceutical and biotechnology companies see the efforts to reform the law on patent damages as an unprecedented effort to enact an entirely new principle into law forcing what is now commonly termed "prior art subtraction." Under this new principle, the courts would be obligated to figure out the inventive essence of the patent by subtracting away any component of an infringing product that was already known at the time the patent was sought. For a novel and non-obvious combination of known materials, there would be no basis for awarding anything more than nominal damages.¹⁸

The perceived assault on patent remedies is more than just a hypothetical concern and the response of the pharmaceutical and biotechnology industries is no reflexive overreaction. The ferocity of this assault is best illustrated by eBay's attack on patent remedies in its reply brief at the Supreme Court.¹⁹ The eBay brief epitomizes the extremist view on how patent remedies should be disabled or at least diminished. The brief opens with a reasoned argument that in a patent case, after the validity and infringement of the patent has been established, there should be no presumption of irreparable harm.²⁰ Such a presumption, according to eBay, is

¹⁶ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

¹⁷ See Intellectual Property Owners Association, Patent Reform: Comparison Chart on Various Bill Versions (revised Apr. 6, 2006), http://www.ipo.org/Template.cfm?Section=Patent_Reform1&CONTENTID=22028&TEMPLATE=/Co ntentManagement/ContentDisplay.cfm.

¹⁸ See generally Joseph Yosick, Compulsory Patent Licensing for Efficient Use of Inventions, 5 U. ILL. L. REV. 1275, 1281–82 (2001) (illustrating examples where infringers have sought a judicial compulsory license).

¹⁹ Reply Brief of Petitioner, eBay Inc. v. MercExchange, L.L.C., No. 05·130 (U.S. Mar. 17, 2006) available at http://www.abanet.org/publiced/preview/briefs/pdfs/05·06/05·130_Petitioners.pdf.

 $^{^{20}}$ Id. at 2.

contrary to traditional equitable principles.²¹ However, the brief then offers a most disconcerting —because it so crystallizes the extremist agenda for diminishing patent remedies—that reads "[e]ven in an action between private individuals, it has long been held that an injunction is to be used sparingly, and only in a clear and plain case."²² Instead of the current practice where ongoing infringement of a valid patent is typically enjoined, eBay apparently contends that injunctive relief should exist sparingly.

The pharmaceutical and biotechnology industries would offer a simple and direct rejoinder: spare the injunction, spoil the patent system.

On issue of apportionment of damages, the most frequent example of the problematic nature of adopting the principle of "prior art subtraction" comes from the mouth of intellectual property counsel at one of this country's most highly regarded IT-oriented, research-based companies. He has contended that Alexander Graham Bell's invention of the telephone was nothing but putting together things that already existed.²³ A speaker, a few wires, and microphone, among other components, that were already individually well known. To determine a reasonable royalty for someone infringing a patent on the telephone, the principle of "prior art subtraction" would require disregarding all such components that already existed. Take away those things that are prior art to the invention of the telephone, and there is, of course, nothing left upon which to award damages. According to the "prior art subtraction" principle, Mr. Bell didn't really deserve much of anything for inventing the telephone.

Having sketched the battleground over patent remedies, it could readily be concluded that the debate is an irreconcilable one between two polar extremes – one side calling for radical reforms, the other calling for the patent system to be left untouched. One might rationally ask if the truth were somewhere in the middle – or is the honest truth that one extreme view of the need for reform is correct and the other plain wrong.

My thesis for the remainder of this talk is two-fold. First, the truth does not lie in the middle. In a certain fundamental sense, neither side should compromise on its stance. Second, perhaps in defiance of all logic, in the most important sense, both extremes have it right. This is a time for radical reform of the U.S. patent laws and it is a time when we must leave the *effectiveness* of the patent system untouched. The challenge Congress really faces today is how to radically reform the patent laws, going after the imbalances and unfairness that the IT sector has persuasively identified, but leave the effectiveness of the patent system untouched. Compromises, or timid and ineffectual reforms to the patent laws, just will not suffice to redress real concerns over the patent system and will not address the significant root causes for the discontent.

To understand why this is not the time for half-hearted efforts at patent reform, we need to step back and examine what has happened to our patent system over the last five to ten decades. The United States has had a patent system for almost twenty-two decades. To date, 108 Congresses have helped craft our current patent

 $^{^{21}}$ Id. at 7.

²² Id. at 7 (quoting Rizzo v. Goode, 423 U.S. 362, 378 (1976)).

²³ See U.S. Patent No. 174,465 (filed Feb. 14, 1876).

laws.²⁴ The system has grown well beyond the imagination of the members of the 1790 Congress that enacted the first patent laws. Patents issue today in vastly greater numbers than even a few decades ago.²⁵ A growing backlog of work for patent examiners continues to lengthen the time needed to get a patent to issue.²⁶ Inventions are made today in entirely novel areas of technology and much invention that takes place has an unprecedented level of complexity, arising in part from the incorporation of diverse and interdependent technologies.²⁷

Visitors to the Old Patent Office Building, which now houses the National Portrait Gallery, can look at how relatively simple the work of the Patent Office once was simply by wandering through the display patent models. For the most part, 19th century patent examination consisted of the inspection of some simple mechanical contrivance, represented either by a patent model or a patent drawing, and then rummaging through a set of "shoes" housing previously issued patents in order to assure that something truly novel had been created.

Today, a factory producing either a modern biotechnology product or computer chip is a billion dollar creation that typically incorporates an array of innovation. Patent lawyers sometimes face an immense task to even define the various patentable innovations arising from a complicated, interdependent system, much less faithfully describe them in cogent patent applications. For the intricate and specialized technologies that spawn today's complicated patent applications, it goes without saying that the 19th century system for examining patent applications has a near impossible task delivering the same level of quality and thoroughness that was possible when most of what a patent examiner needed to know could be discerned from inspecting a physical model or drawing of a purported invention. Simply stated, patent examiner training and the resources available to patent examiners have not kept pace with the change in the way technology works and the way the patent system works and is now used by inventors.²⁸

Id.

²⁴ See Markman v. Westview Instruments, 517 U.S. 370, 373 (1997).

Congress first exercised this authority in 1790, when it provided for the issuance of "letters patent," Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109, which, like their modern counterparts, granted inventors 'the right to exclude others from making, using, offering for sale, selling, or importing the patented invention,' in exchange for full disclosure of an invention.

²⁵ Office of Electronic Information Products Patent Technology Monitoring Division (PTMD), U.S. Patent & Trademark Office, U.S. Patent Statistics Chart Calendar Years 1963–2004, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Apr. 18, 2006) (noting an increase in the number of patents issued from 48,971 in 1963 to 181,302 in 2004).

 $^{^{26}}$ Id. (indicating that in the early 1960s, the number of patent applications did not exceed 100,000 and that in 2004, the number of patent applications exceeded 380,000 while less than 200,000 were issued).

²⁷ See FISCAL YEAR 1998 USPTO ANNUAL REPORT: A PATENT AND TRADEMARK OFFICE REVIEW: IDEAS THAT BECOME VALUABLE INNOVATIONS, *available at* http://www.uspto.gov/web/offices/com/annual/1998/a98r·2.htm (noting that the largest increase in patent applications come from high technology areas).

²⁸ Improvements Needed to Better Manage Patent Office Automation and Address Workforce Challenges: Testimony Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 109th Cong. 3 (Sept. 8, 2005) (statement of Anu K. Mittal, Directory Science and Technology Issues and Linda D. Koontz, Director Information Management Issues), available at http://www.gao.gov/new.items/d051008t.pdf.

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The undeniable consequence is that more patents of questionable merit now issue.²⁹ We also know that the sheer volume of questionable patents has grown because the volume of patenting today is enormous. When existence of questionable patents reaches a "critical mass" surrounding any industry or technology, it creates a profound impact on the freedom of action needed to implement cutting edge technology.³⁰ It is one level of concern for a business to confront an occasional patent of questionable merit; it quite another to face a hoard of such patents and hope to successfully surmount them all. Because of differences in the absolute number of potentially relevant patents issuing in various technology sectors, the issue of inadequate patent quality hits some industries quite differently from others.

An industry-relevant analogy may help illustrate how absolute numbers of issuing patents causes the patent system to operate differently in different industry sectors. Among information technology companies, an individual patent is often like an individual fire ant. A typically sized IT company attempts to arm itself for battle against its innovative competitors by amassing fire ant-like patents in the thousands. Indeed, for such an IT company, issuing more than 1000 patents in a year is not uncommon. If you have amassed enough "fire ant" patents, you are prepared to battle a competitor-foe of almost any size.

In the pharmaceutical industry, the absolute number of patents issued to a typically sized company is typically an order of magnitude less. Most patents are sought for products that never make it to market, cutting the effective size of the patent portfolio down by another order of magnitude. In terms of patents that stand in the path of a generic pharmaceutical competitor seeking to market an outright copy of an innovative medicine, the effective size of the patent portfolio of most pharmaceutical companies is reduced by yet another order of magnitude.

What this means is that the patents that turn out to be commercially meaningful are very few in number, sometimes only a solitary relevant patent exists. Such solitary patents need to function like a gorilla in terms of their strength and effectiveness in terms of standing in the way of a generic copycat.

Allow me to take a close-to-home example. My company is in the midst of a patent struggle over a four-billion-dollar-a-year product. The FDA laws force us to list the relevant patents on the drug standing in the way of a generic pharmaceutical company. We have only a single relevant patent listed with the FDA. It has proven, however, to be one gorilla-sized patent that is successfully keeping several generic drug manufacturers off the market and will for the remainder of this decade and beyond. If the patent system operated so that pharmaceutical industry patents of this type could never have a size or strength bigger than that of a fire ant – such that the generic drug companies could evade the few such patents protecting any innovative medicine – my company would go out of business altogether.

²⁹ Office of Audits, PTO Audits Division, U.S. Dep't of Commerce Office of Inspector General, *Patent and Trademark Office Patent Quality Controls Are Inadequate*, Audit Report No. PTD-9977-7-0001, at 3 (Sept. 1997), *available at* http://www.oig.doc.gov/oig/reports/1997/USPTO-PTD-9977-7-09-1997.pdf.

³⁰ Wendy H. Schacht & John R. Thomas, *Patent Reform: Innovation Issues*, CRS Report for Congress, at 6–7 (July 15, 2005), *available at* http://patentlaw.typepad.com/patent/RL32996.pdf (highlighting the main arguments concerning the deleterious effect of low-quality patents).

The flip side of this analogy is equally frightening to an IT company. A complex IT system may have 100 patented innovations – sometimes even more – incorporated into the system. While an IT company might be able to successfully handle one or even a few "fire ant" patents that could stand in the path to commercialization of such a system, it dreads the prospect that one or two gorilla-sized patents might bar the path forward to commercialization.

When a patent of questionable merit cannot be effectively challenged in the courts or back in the patent office, it is effectively transformed from fire ant to gorilla. Patent quality and civil justice are critical to the IT industry to prevent such a transformation – even for a small number of patents.

When a valid and infringed gorilla-sized patent cannot be effectively enforced in the courts, it is transformed to a commercial weapon that is no more potent a weapon than a solitary fire ant. Predictable enforcement of valid is a like civil justice issue for patent owners.

What does this analogy mean to patent reform? The fight over patent remedies can be viewed as an attempt by the IT industry to assure that questionable patents that cannot be effectively challenged can never grow to the size and strength of a gorilla and the response of the pharmaceutical industry can be viewed as an effort to assure that the handful of gorilla-sized patents on which it depends for its survival do not get transformed through patent reform into a tiny tribe of fire ants. For both sides in the patent reform debate, the common issues are patent quality and civil justice. Valid patents need assured enforcement with substantial and predictable consequences meted out on infringers.

Questionable patents require legal means for effectively testing their validity and effectively weeding out the unworthy ones. If the threat of enormous patent damages, including the threat of punitive damages, is coupled with ineffective opportunities to demonstrate patent invalidity, an accused infringer faces the same type of civil justice issues that bedevil other areas of civil litigation.³¹ Being forced to settle because there is little prospect for a fair fight against a patent of questionable validity is the antithesis of a fair and balanced patent system.

Civil justice reforms that assure questionable patents can be challenged effectively is not inconsistent with the goal of biotechnology and pharmaceutical industry interests that want patents to be enforceable just like other forms of property rights. When someone is engaged in an ongoing trespass of a property, the remedy – as a general principle – should be eviction and damages sufficient to make the property owner whole with respect to the losses arising from the trespass.

The patent owner today faces civil justice issues that are just as problematic as the concerns raised by the patent challenger. No system of property rights survives if the cost of procuring and enforcing those rights exceeds the underlying value of the

³¹ See Blandy v. Griffith, 3 F. Cas. 675, 679 (S.D. Ohio, 1869) (The court held that the rights secured by patent were real and should not be overthrown where there existed reasonable solutions in favor of their validity. In particular, the court noted, "[t]his principle should be steadily borne in mind by those to whom is entrusted the administration of civil justice."); see also Johns Hopkins Univ. v. Cellpro, 978 F. Supp. 184, 196 (D. Del, 1997) (wherein the court at the same time commented on its inability to bring the matter to a swift determination and awarded treble damages for the deliberate and bad-faith infringement of the patent in question).

property. Sadly, many patents that issue today are effectively unenforceable because the cost of enforcement exceeds that economic value.

Patent owners and patent challengers alike have a common interest in certainty and predictability of a patent system that ought to represent a common objective for reform. If a patent is to operate like any other property right in terms of value for its owner and respect by a could-be trespasser, it had better be reasonably clear to a potential trespasser where the metes and bounds of those rights lie. If a patent law is no more predictable than a flip of a coin on the dispositive issues of validity, infringement and enforceability, for whom is the patent system an incentive to invest and in what way does it serve those seeking to respect valid patent rights of others? As just one example, claim construction reversals at the Federal Circuit, after a trial court has thoroughly considered all of the issues is said by some to approach fifty percent, almost that same as the proverbial coin toss.³²

Civil justice for patent litigants requires a patent system that functions as an effective property rights system – with mechanisms for cost-effective, prompt, and final determinations of what the valid scope of the property rights are, as well as predictability and certainty in enforcing such valid rights.

There is one final dimension to the debate over the type of reforms that would be wise for U.S. interests. That is the "flat world" issue. When we debate domestically the question of whether the United States grant injunctions in patent cases only sparingly or when we discuss whether or not, for civilization-changing inventions like the telephone, "prior art subtraction" should limit an inventor to nominal damages, the remainder of the world is both watching and listening. We are one of 150 countries in the World Trade Organization bound by the TRIPs agreement to observe a set of minimum standards for IP protection.³³ What we do in the United States with our IP laws, will not go unnoticed in the 149 other WTO countries. Many of these countries are not inherently inclined to provide strong and effective protection for patent rights.³⁴

What might our global IP village look like if we make extremist reforms to our patent law that dilute or diminish remedies for infringing a valid patent? Imagine for a moment that in many countries patent and copyright infringement, as well as

³² See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Radar, J., dissenting) ("Nonetheless, one study shows that the plenary standard of review has produced reversal, in whole or in part, of almost 40% of all claim constructions since Markman I.").

³³ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994,

Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) (setting minimal standards of protection of intellectual property rights to be recognized by all Member countries of the WTO).

³⁴ See, e.g., Nermien Al-Ali, *The Egyptian Pharmaceutical Industry After TRIPs: A Practitioner's View*, 26 FORDHAM INT'L L.J. 274, 282 (2003).

In addition to the high levels of poverty and the weak infrastructures, developing countries needed to reform their legal systems to provide adequate patent protection for pharmaceuticals. Since the developing countries had denied patent protection to pharmaceuticals for so long, their legal systems lacked the requisite financial resources and knowledge to handle patent applications relating to pharmaceuticals.

trade secret misappropriation, was only enjoined sparingly. Imagine damages were constrained by principles such as "prior art subtraction."

Take the hypothetical example of a product that is trademarked "Doors" that is sold as a computer operating system sold by a very successful high-tech firm "X?" Let's suppose that in some far-off land, a pirate company "P" has copied Doors in order to sell its own version of Doors. It makes a colorable claim that its product is an improvement on Doors because it has added a few modest features that meet consumer needs in its home country, "TW."

Pirate P's arguably improved version of Doors obviously infringes both patent and copyrights of firm X in country TW, but in country TW the extremist views of the law on both damages and injunction applies. These remedies are only granted sparingly, certainly not in the case where the pirate P has some improved features they claim to have added to Doors. Additionally, any damages for ongoing infringement of firm X's IP rights must subtract away all technology that was previously known. So, when the courts of country TW are finished, it is decided that for only a few yuans per copy, pirate P gets the right to continue supplying the domestic market for Doors in country TW.

This vision of IP systems without effective remedies is not survivable for anybody in the innovation-dependent industries. However, as we ponder how we make needed changes to our patent law, it is absolutely critical, that we look all across our global IP village and take account of not just what our domestic patent reforms would mean if they were globalized, but what precedents such reforms would set for all systems of IP protection.

If there is a case for patent reform across industry sectors based in large measure on increasing patent quality and advancing civil justice, there is much we can learn from recent patent litigation about type of specific reforms that are needed. Three recent patent cases demonstrate that discontent over the current patent laws is in no way industry-specific.

The first of these three cases forced millions of Americans, members of Congress included, to contemplate the near unthinkable: life without a BlackBerry.³⁵ The maker of the BlackBerry had what appeared to be a full and complete opportunity to litigate to a final judgment the validity of a collection of patents, and it was found to be an infringer of valid patents.³⁶ It then settled the case for six-hundred million dollars, what the patent owner likely alleged was a mere a drop in the bucket given the supposed profits that had been reaped from the infringement.³⁷ But, wait a minute. What is the real story behind those patents and their legal merit? As the \$600,000,000.00 check was being cashed by the patent owner, the United States Patent and Trademark Office was in (and remains today in) the process of possibly canceling those patents in a reexamination.³⁸ Which is it, truly valid patents or

³⁵ See, e.g., NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

³⁶ See NTP, Inc. v. Research in Motion, Ltd., 397 F. Supp. 2d 785, 786 (E.D. VA 2005).

³⁷ See Mike Hughlett, BlackBerry Suit Settled: \$612.5 Million Deal Keeps Network Active, CHI. TRIBUNE, Mar. 4, 2006, at C1; Inquirer Staff, Blackberry Way Turns Profit Into Loss, THE INQUIRER, Apr. 6, 2005, available at http://www.theinquirer.net/?article=22369.

³⁸ See Posting of Dennis Crouch to Patently-O: Patent Law Blog, http://patentlaw.typepad.com/patent/2006/03/the_war_is_over.html (Mar. 6, 2006).

worthless paper? An accused infringer should not be forced to pay six-hundred million dollars with that fundamental question remaining undecided.

A second perverse patent case is still ongoing and it demonstrates that patent owners are being shortchanged in the civil justice department in a manner similar to patent challengers. This case involves a valid and infringed patent owned by Purdue Pharma.³⁹ In pharmaceutical industry terms, the Purdue Pharma patent was a gorilla-sized patent, covering its top selling product, OxyContin and the only patent standing in the path of another company seeking to come to market.⁴⁰

The Federal Circuit affirmed a lower court ruling that Purdue Pharma's OxyContin patent was unenforceable. Purdue Pharma had allegedly engaged in inequitable conduct. The company responded to this decision by laying off 825 employees.⁴¹ This amounted to thirty-eight percent of its workforce because this one gorilla-sized patent was taken down and exclusivity lost on its leading product.⁴²

What happened several months after this devastating court loss? The Federal Circuit issued another opinion on reconsideration. This time the court said, in effect, "never mind," it may all have been a big mistake.⁴³ On second thought the Federal Circuit saw nothing in the record of any intent to deceive or mislead the patent examiner. The patent did not appear to be unenforceable after all and it sent the case back to the District Court to decide what to do with it.⁴⁴

This is clearly not how a property rights system ought to work. There are 825 employees who must be similarly convinced that this is not how a system of intellectual property rights ought to work. Purdue Pharma shareholders fall into the category of disbelievers that what happened here is justice.

The Purdue Pharma case is not an isolated example of the "inequitable conduct" doctrine running amuck. In a third case, Aventis, another pharmaceutical company, lost a patent to inequitable conduct because it filed a declaration of a world-renowned expert to explain what a word that is commonly used and universally understood in the pharmaceutical science actually means. The expert opined that "peroral" means what essentially every dictionary says that it means.⁴⁵ However, the Federal Circuit found this patent unenforceable⁴⁶ because the declarant, its world-renowned expert, who stands accused of doing nothing more than being truthful, failed to tell the patent examiner that he had a consulting relationship for the company.⁴⁷

The court found inequitable conduct under what appears to be a new duty of candor, applying a "might-have-been-asked, should-have-been-answered" standard,

⁴⁷ Id. at 1194.

³⁹ See Purdue Pharma L.P. v. Endo Pharms., Inc., 410 F.3d 690 (Fed. Cir. 2005), vacated, Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1137 (Fed. Cir. 2006) (vacating and remanding the judgment regarding finding of inequitable conduct).

⁴⁰ See John Christoffersen, Purdue Pharma to Lay Off 825 Employees, ABCNEWS, July 1, 2005, http://abcnews.go.com/Business/wireStory?id=900621&CMP=OTC-RSSFeeds0312.

⁴¹ *Id.*

 $^{^{42}}$ Id.

⁴³ Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1137 (Fed. Cir. 2006) (vacating and remanding the judgment regarding finding of inequitable conduct).

⁴⁴ Id.

⁴⁵ Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1184 (2006); *see also* THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1309 (4th ed. 2000) ("peroral: through or by way of the mouth").

⁴⁶ *Ferring*; 437 F.3d at 1195.

for deciding what must be told to a patent examiner. In both the Purdue Pharma and Aventis cases, what pharmaceutical company would ever have invested in the innovative medicines covered by these patents if it knew in advance that its exclusivity would likely be shattered. even though the patents appeared to be fully valid and unquestionably infringed?

The case for making radical reform to the patent laws and the case for leaving the patent system as an effective incentive for innovation untouched are equally strong. Having reconciled these two premised and exemplified some of the patent quality and civil justice issues, what exactly should be done by Congress?

First of all, patent law must be made simple, objective and transparent. We have too much complexity in our patent law in part because we have too many issues in our patent law. We have either the blessing or the curse of 108 Congresses before the present one crafting and embellishing our current patent system with all manner of principles and doctrines. As time has gone on, we have attempted to reform our patent laws by adding new things to it, most recently the 1952 addition of a "best mode" requirement for disclosure. More than 200 years of judicial decisions have afforded the courts the opportunity to engraft new doctrines onto patent law and then refine and nuance them.⁴⁸

For these and other reasons, we have today the most non-transparent patent system anywhere in the world. Non-public information by the bucketload can be relevant and is sometimes dispositive to determining the true patentability of any Any patent that is picked up today, no matter how adequate the invention. disclosure of the invention appears to be or how complete the identification of the relevant prior art appears to be, it cannot be known with certainty that the patent has an adequate disclosure or that the prior art has been fully identified.

The United States wins the prize for the world's most subjective patent system. Patent validity depends upon knowing what certain individuals thought and when they had those contemplations, what certain individuals did in secret and when those secret actions took place, and what subjective beliefs were formed and when. These occult issues must be addressed in order to decide not only which side will win in a patent case, but also how much an infringer may be assessed in damages. Unlike the patent law in most countries outside the United States, a person skilled in the technology and with an understanding of the patent law cannot pick up a patent today, reference only publicly accessible information, and come to a final and complete assessment of whether or not a patent is valid.

Most importantly, today we have a patent system that not only examining patents too slowly, but the pace of patent examination is continuing to decelerate. Patent examination today is a nineteenth-century creation that is fundamentally unchanged from the way it was conducted in the nineteenth century, including how rapidly patent applications proceed through the patent examination process and the lack of any meaningful way for the public to participate in this process, especially where clear-cut mistakes have been or are being made by the patent examiner.

How do we know these root causes are real causes of distress over the operation of the patent system? We can now reference a legion of careful studies and analyses of root causes of discontent over the patent system and proposed solutions. An

⁴⁸ See Jason O. Watson, A History of the United States Patent Office, Apr. 17, 2001, http://www.m-cam.com/~watsonj/usptohistory.html.

October, 2003 FTC report affirmed the need to maintain a strong patent system, but supported making radical reforms.⁴⁹ The same can be said of the National Academy of Sciences that issued a report a few months later, following its several-year study of the patent system.⁵⁰ The American Bar Association's Intellectual Property Law Association Section, which for many years was seen by some as a more a defender of the status quo than a bastion of support for significant patent reforms, has now issued a sixty-four page white paper, available on its website, that explains the need for radical surgery on our patent laws.⁵¹ During 2003 and 2004, the American Intellectual Property Law Association, guided by the work of a blue ribbon committee, its Special Committee on Patent Legislative Strategies, came to a very similar set of conclusions.

Each of these four efforts reflected serious and intensive studies of the patent system. AIPLA's Special Committee on Patent Legislative Strategies, for example, proposed making our system more transparent and objective through comprehensive reforms.⁵² Its proposed reforms included (1) first-inventor-to-file reforms that limit prior art to publicly accessible art; (2) eliminating the best mode requirement to disclose certain of the inventor's subject contemplations; (3) removing the secret prior use exception that can invalidate a patent if the secret prior use was done domestically, but leave the same patent valid if same work was done outside the United States; and (4) eliminating subjective elements from most patent litigation.⁵³ In other words, if an issue of validity, enforceability or willfulness of an infringement of a patent references an individual's state of mind or information not accessible to the public, it is pushed out of the patent law – or at least to the sidelines in most patent litigation.

Congress, as I indicated earlier, has had a number of hearings on patent reform issues.⁵⁴ A bill has been dropped in the House of Representatives.⁵⁵ We may yet see a bill coming up in the Senate. Thus far, legislative efforts are aligned fairly accurately with recommendations from those four reports on the patent system. The House bill aligns with many of the key recommendations of the Federal Trade

⁴⁹ See Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Oct. 2003, http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

⁵⁰ See Bruce Alberts, President, Nat'l Acad. of Scis., Address at the Academy's 141st Annual Meeting: A World that Banks on Science (Apr. 19, 2004), available at http://www.nasonline.org/site/DocServer/2004address.pdf?docID=109.

⁵¹ The ABA Section of Intellectual Property Law, A Section White Paper: Agenda for 21st Century Patent Reform (revised Sept. 16, 2005), www.abanet.org/intelprop/home/PatentReformWP.pdf [hereinafter ABA White Paper].

⁵² See Letter from Gary Griswold, Past President of AIPLA, to Rep. Lamar Smith, Chairman, H. Subcomm. on Courts, the Internet, and Intellectual Property (June 9, 2005), http://www.aipla.org/Content/ContentGroups/Legislative_Action/109th_Congress/Testimony5/GGOr alStatement.pdf.

 $^{^{53}}$ Id.

⁵⁴ See Oversight Hearing on "Patent Harmonization": Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 109th Cong. (Apr. 27, 2006) (statement of Rep. Smith, Chairman, H. Subcomm. on Courts, the Internet, and Intellectual Property) ("Today the subcommittee conducts its sixth hearing in the 109th Congress on patent reform."), available at http://judiciary.house.gov/OverSight.aspx?ID=235, http://boss.streamos.com/real/hjudiciary/courts/042706.smi.

⁵⁵ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (as introduced June 8, 2005)

Commission,⁵⁶ all the key recommendations of the National Academy of Sciences,⁵⁷ all the key recommendations in the ABA-IPL Section white paper,⁵⁸ and is very consistent with what the American Intellectual Property Law Association sought to have done with the patent system.⁵⁹ When Chairman Smith originally introduced the House bill, there were a few industry-specific concerns. There was a provision on compensatory damages that talked about limiting damages to the "inventive contribution," raising concerns that this could codify "prior art subtraction".⁶⁰

Another provision in the House bill on injunctive relief that required a court to consider the fairness in light of all facts and interests of relevant parties associated with the invention.⁶¹ Such language would be totally new to the patent statute and would move the law some distance beyond the so-called "four factor test" for deciding whether someone is entitled to an injunction.⁶²

From the pharmaceutical industry viewpoint the proposed injunction reform is particularly problematic. A generic drug company might explain to a court that it is going to give the patients a 25% discount on their generic version of an innovative medicine if the court were to authorize them to engage in the ongoing infringement of a valid patent. If a court were to decide that allowing the ongoing infringement was a "fair" result to the innovator because the innovator had already made enough money under the patent, a full 200 years of U.S. patent law principles would be undone.

On July 26 of last year, Chairman Smith announced a substitute bill that many hailed as making significant improvement.⁶³ First, the potential for "prior art subtraction" was eliminated.⁶⁴ Second, the troublesome injunction provision was

⁵⁶ Compare Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (as introduced June 8, 2005), with Federal Trade Commission Report, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, October 2003, http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

⁵⁷ Compare Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (as introduced June 8, 2005), with NAT'L ACAD. OF PUB. ADMIN. REPORT TO CONGRESS, U.S. PATENT AND TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY, (2005), http://www.napawash.org/Pubs/PTO-8-25-05.htm.

 $^{^{58}}$ Compare Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (as introduced June 8, 2005), with ABA White Paper, supra note 51

⁵⁹ Compare Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (as introduced June 8, 2005), with Patent Act of 2005: Hearing on H.R. 2795 Before Subcomm. on Courts, the Internet and Intellectual Property of the Comm. on the H. Judiciary, 109th Cong. (2005) (statement of Gary Griswold, Past President of the American Intellectual Property Law Association).

⁶⁰ ABA White Paper, *supra* note 51, at 39.

⁶¹ ABA White Paper, *supra* note 51, at 45.

⁶² Univ. of Tex. v. Camenisch, 451 U.S. 390, 392 (U.S. 1981) (listing the following four factors to be considered by federal courts when granting a preliminary injunction: "whether the plaintiff will be irreparably harmed if the injunction does not issue; whether the defendant will be harmed if the injunction does issue; whether the public interest will be served by the injunction; and whether the plaintiff is likely to prevail on the merits.").

⁶³ See Amendment in the Nature of a Substitute (proposed July 26, 2005), http://www.ipo.org/Template.cfm?Section=Patent_Reform1&CONTENTID=19482&TEMPLATE=/ContentManagement/ContentDisplay.cfm

⁶⁴ See Id; cf. Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2d Sess. 2006) (omitting the section on combinational damages from the bill entirely).

gone.⁶⁵ In response to the substitute, a coalition of about thirty companies banded together and proposed basically that the Smith substitute bill be enacted, with some relatively modest additional features added to the bill.⁶⁶ Indeed, this so-called coalition text from last September has now garnered support from the IPO, the Intellectual Property Owners Association,⁶⁷ and the AIPLA.⁶⁸ Except for some relatively secondary issues, the coalition proposal aligns with the views in the white paper of ABA-IPL section.⁶⁹

Several of the substitute bill's most significant features were supported by the Business Software Alliance, which is clearly aligned with its IT-company members.⁷⁰ All but one key provision appeared to get some support from some elements of the university community.⁷¹ A collection of academics, consisting of twenty-five law school professors, got together and proposed some of these reforms and had some reform ideas of their own.

These efforts aim for an objective patent system, a transparent patent system, and one that can work more rapidly. In addition, the reform effort does squarely tackle the issue of advancing civil justice for patent litigants. The coalition text and the Smith substitute both would make changes in the manner in which venue in patent cases would be administered.⁷² These changes are proposed with the idea that

⁶⁶ See Letter from the Coalition for Patent Reform, to Hon. Lamar S. Smith, Chairman, H. Subcommittee on the Courts, the Internet and Intellectual Property (Sept. 1, 2005). http://www.ipo.org/Template.cfm?Section=Home&CONTENTID=20145&TEMPLATE=/ContentMan agement/ContentDisplay.cfm; see also AIPLA.org, A Coalition for 21st Century Patent Law Reform: Balanced Initiatives to Advance Quality and Provide Litigation Reforms September 1, 2005, http://www.aipla.org/Content/ContentGroups/Legislative_Action/109th_Congress/House1/CoalPrinto fHR2795.pdf; Intellectual Property Owners Association, Patent Reform: Comparison Chart on Bill Versions (revised Various Apr. 6. 2006). http://www.ipo.org/Template.cfm?Section=Patent_Reform1&CONTENTID=22028&TEMPLATE=/Co ntentManagement/ContentDisplay.cfm (comparing the original H.R. 2795, the coalition's proposed changes, and the newly proposed H.R. 5096).

⁶⁷ See Patent Law Reform: Patent Injunctions and Damages: Hearing Before the S. Judiciary Comm. on Intellectual Property, 109th Cong. (2005) (testimony of Jeffrey J. Hawley, President, Intellectual Property Owners Association).

⁶⁸ See Patent Act of 2005: Hearing on H.R. 2795 Before Subcomm. on Courts, the Internet and Intellectual Property of the Comm. on the H. Judiciary, 109th Cong. (2005) (statement of Gary Griswold, Past President of the American Intellectual Property Law Association).

⁶⁹ See ABA White Paper, supra note 51.

⁷⁰ Amendment in the Nature of A Substitute to H.R. 2795, the Patent Act of 2005: Hearing on H.R. 2795 Before Subcomm. on Courts, the Internet and Intellectual Property of the Comm. on the H. Judiciary, 109th Cong. (2005) (statement of Emery Simon, counselor to Business Software Alliance) available at http://www.bsa.org/usa/press/newsreleases/Testimony-Reform-Bill.cfm.

⁷¹ Before Subcomm. on Courts, the Internet and Intellectual Property of the Comm. on the H. Judiciary, 109th Cong. (2005) (statement of Charles E. Phelps, Provost, University of Rochester), available at http://www.aau.edu/intellect/PhelpsPatRefTest_7_26_05.pdf

 72 Intellectual Property Owners Association, Patent Reform: Comparison Chart on Various Bill

 Versions
 (revised Apr. 6, 2006),

 http://www.ipo.org/Template.cfm?Section=Patent_Reform1&CONTENTID=22028&TEMPLATE=/ContentManagement/ContentDisplay.cfm

⁶⁵ See Amendment in the Nature of a Substitute (proposed July 26, 2005), http://www.ipo.org/Template.cfm?Section=Patent_Reform1&CONTENTID=19482&TEMPLATE=/Co ntentManagement/ContentDisplay.cfm *But see* Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2d Sess. 2006) (reintroducing the section on injunctions as originally proposed in the bill of July 8, 2005).

if neither the plaintiff nor the defendant has any particular connection, by evidence, witnesses, or otherwise, to a particular venue, a court would be required to transfer venue.

Punitive damages reforms that would eliminate willful infringement allegations from essentially all patent litigation, was included. Another prime objective in the civil justice system reform context was to have compensatory damages that accurately codify *Georgia-Pacific* factor thirteen, which mandates apportionment of damages away from a patented invention when other contributions of economic value are present, particularly when the infringing product is covered by a multiplicity of patents that contribute value.⁷³

Pre-grant submissions of prior art and post-grant review of patents assure that, as the patent is being examined and after the patent is being examined, the public has the maximum opportunity to have an impact on the patenting process. The publication of all applications at eighteen months also helps the patent system be more fully transparent.

What would the patent system actually be like if either the Smith text or a substitute of the coalition text became law? It would largely meet the twin goals of transparency and objectiveness. The aforementioned goal would be largely met - ifyou were a trained patent professional, and you were skilled in the technology of the invention, you could actually pick up a patent or a published patent application, review it, reference only publicly accessible information, and essentially make a final and complete determination on every issue of patentability.74 In determining validity, there would typically be no need to talk to the inventors about when they did their work or what contemplations that had about the various modes of carrying out the invention.⁷⁵ Invention dates would not be relevant for any purpose.⁷⁶ The reforms would collectively produce an amazing transformation of the patent system. just from the standpoint of required discovery to assess validity. This alone could greatly moderate patent litigation costs. Since evidence related to the inventor's state of mind and activities leading up to filing the patent would not be relevant to validity, such evidence would not need to be discovered and these complicated and subjective determinations would be erased from the law.

Under the Smith bill and the coalition-supported proposals, patents would always be open to *inter partes* post-issuance revocation procedures. The key reform creates a new post-grant opposition system. The public would be afforded a ninemonth window to challenge a patent immediately after issuance on any issue of patent validity. If a questionable patent issued that should not have been issued, that patent can be eliminated during the opposition.

A statutory requirement that the post-grant opposition be completed in one year, would, by itself, work an amazing transformation of the manner in which the public could participate in the administrative side of the patenting process.

⁷³ Ga.-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc., 318 F. Supp. 1116, 1120 (1970).

⁷⁴ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

⁷⁵ *Id. But see* Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2d Sess. 2006) (eliminating the first-to-file provision among others).

⁷⁶ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). But see Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2d Sess. 2006) (eliminating the first-to-file provision among others).

Perhaps the keystone reform would offer the inventor an incentive to obtain a fully valid patent. An inventor today, under the existing duty of candor and good faith,⁷⁷ has no real incentive to obtain a wholly valid patent.⁷⁸ The inventor has an incentive to do two things in order to proactively defend against allegations of inequitable conduct. First, there is the incentive to tell the Patent Office everything, no matter how trivial its relationship to patent examination might seem. If a person under the duty of candor withholds any information, no matter how seemingly trivial, the withholding can be later alleged to have been material, permitting an inference of intentionally deceptive conduct.⁷⁹ Second, there is an incentive to say nothing that would be meaningful to the patent examiner in understanding the invention and its relationship to the prior art.⁸⁰ Anything said about what any piece of prior art might mean, or what the state of the art might be, can be used to demonstrate that the inventor misrepresented the whole truth – there was something more or something different that should have been said.⁸¹ Under today's duty of candor and good faith, the practical incentive is to minimize the amount of candor, not guide the patent examiner in any substantive way that might assure that the patent examination is the most complete and most accurate that it can be.

The Smith substitute turns this state of affairs upside down. If a patent is fully valid, it cannot be attacked as having been obtained through inequitable conduct. The defense cannot be pled unless the accused infringer has already invalidated one or more claims of the patent. This "valid patent safe harbor" from inequitable conduct allegations will mean that the inventor has the opportunity to work with the examiner and effectively say, "Let's make sure I get a valid patent."

In brief summary, Chairman Smith has identified three intertwined pillars of patent reform. First are the transparency and objectiveness reforms. Second, are the public participation reforms, the most sweeping of which is the post-grant opposition proceeding in which the public can get the Patent Office to correct any mistake made in issuing a patent. Third is the incentive to obtain a valid patent by fixing the law of inequitable conduct.

In my view, it is the first and third pillars that make the second pillar both possible and powerful. The transparency and objectiveness reforms make it possible for all issues of patent validity to be efficiently decided by the Patent Office in the post-grant opposition proceeding. Inequitable conduct reforms will mean better quality examination, based upon true candor and good faith going both ways during the original examination. This should reduce the number of oppositions by reducing the number of questionably valid patents. This should make the burden on the Patent Office of conducting post-grant oppositions more sustainable. In addition, it means that patent owners will not face the specter of a huge increase in inequitable conduct allegations based upon conduct during the post-grant opposition, at least where the resulting patent is fully valid. Finally, the Smith substitute would enact

^{77 37} C.F.R. § 1.56 (2006).

⁷⁸ Perspectives on Patents: Hearing Before the S. Judiciary Comm. on Intellectual Property, 109th Cong. (2005) (testimony of Robert A. Armitage, Senior Vice President and General Counsel of Eli Lilly and Company), *available at* http://judiciary.senate.gov/testimony.cfm?id=1475&wit_id=4230.

^{79 37} C.F.R. § 1.56.

⁸⁰ Jeffrey G. Sheldon, How to Write a Patent Application, at § 7, § 7.5.7.2 (PLI, 2005)

⁸¹ Id.

the third pillar reforms by placing the opposer under a duty of candor and good faith, which is needed to provide protection during the opposition against opposer misconduct that might otherwise result in wrongful cancellation of patent claims.

It remains possible, but far from certain, that what today appears as a great patent divide between those seeking radical reform of the patent laws and those desiring to leave the effectiveness of the patent system untouched can be bridged. However, assuming that it can be bridged, what ought to be done after Chairman Smith's three pillars become law? While the three pillars would afford comprehensive reform, one of the most important problems the patent system faces today is left untouched: the nineteenth-century paradigm for patent examination.

Why do we have a patent office that is a real place, a billion-dollar edifice in Alexandria, Virginia? For those of us of a certain age, we actually remember why we have a physical patent office. A physical patent office was established because that is where the paper was kept. Millions of pieces of paper were housed so that prior art could be searched. Those documents were organized and classified so examiners and the patent professions could search the prior art efficiently. Without a physical patent office, there was no feasible way in which to conduct a high-quality patent examination.

When patent examination itself was first created, the patent shoes were designed for manual searching by human hands in order to find relevant prior art. Only after fingering through the patent shoes, looking mostly at patent drawings, could the patent examiner determine whether an invention was patentable.⁸²

In the Age of Google, this does seem a bit quaint. What is clear, however, is that the Patent Office no longer has a monopoly on the information needed to examine. Indeed, it is not just that the monopoly is gone, the relevance of a patent office as a physical place for housing and accessing the information needed for patent examination has all but vanished. The premise of the a patent office, built on the paradigm of shoes containing issued patents to be searched, if not vanished now, will be in five to ten years

The Patent Office today does have a monopoly or even primacy on the information that's needed to examine; that information is globally accessible.⁸³ As noted earlier, the job of the patent examiner is further complicated by the fact that inventions are more complicated; the underlying technology on which they are based is complicated.⁸⁴ More people are patenting more things,⁸⁵ especially in high

⁸² See KENNETH W. DOBYNS, THE PATENT OFFICE PONY: A HISTORY OF THE EARLY PATENT OFFICE 193 (Sergeant Kirkland's Press 1994), available at http://www.myoutbox.net/popch31.htm.

⁸³ See Google, www.google.com (last visited Apr. 19, 2006); Yahoo!, www.yahoo.com (last visited Apr. 19, 2006); United States Patent and Trademark Office Homepage, http://www.uspto.gov/ (last visited Apr. 19, 2006).

⁸⁴ Dan Ness, *Electronics Still Widely Seen As Too Complicated, but Parents Tend to Be More Philosophical*, Oct. 18, 2004, http://www.technologyuser.com/pages/info/tup_dates/tupan04_d06.htm ("Consumer electronic products are more complicated than they ought to be, according to fully a quarter of the American population.").

⁸⁵ Office of Electronic Information Products Patent Technology Monitoring Division (PTMD), U.S. Patent & Trademark Office, U.S. Patent Statistics Chart Calendar Years 1963–2004, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Apr. 18, 2006) (noting an increase in the number of patents issued from 48,971 in 1963 to 181,302 in 2004).

technology areas, where more patents are connected to one another and what is patented is an aspect of a complex, multi-technology system.⁸⁶

Patents today are more consequential. There are vastly greater consequences today for getting the patent process wrong and failing to obtain a valid patent or for misjudging whether a competitor has succeeded or failed in obtaining valid patent protection.

So if we fast forward from the halcyon days of the nineteenth century to the IPsupercharged twenty-first century and ask, "What do patent examiners need in the twenty-first century to effectively examine patent applications?," the answer is very clear. They have little need for access to mounds of paper to be housed in classified patent shoes. They need legal training and experience in applying that training to complex technologies. They need a thorough understanding of patentability requirements and their application. They need technical expertise in the field of the invention – or someone to guide them through the patent application in a manner to assist in acquiring that expertise. They need continuity from the beginning to the end of the process - and they need that process to run from start to finish in a reasonable time period. They need sufficient time - and the amount of time they need is dependent upon the amount of guidance they can get to learn and synthesize what they need to know. They need sufficient time to understand today's more complicated patent applications. They need to digest what is really being claimed and the pertinence of the prior art.

One way of looking at what patent examiners need is that it is everything that is in short supply in the Patent Office, and exactly what most inventors and their patent counsel have in much greater abundance. In many respects, the change in the way the world of invention works means that a complete reversal of roles has transpired. Back in the old, twentieth-century days, it used to be that you'd actually go talk to a patent examiner to learn about the prior art and to understand the field of technology. The examiner could guide an applicant to the closest prior art.

So what should this near role-reversal mean in the future? It can only mean one thing, if patent quality is to be enhanced: increased applicant responsibility. This is a term Director Dudas used in his April 2005 Senate testimony on patent system reform.⁸⁷ He is working to push this concept forward through a PTO proposed rule package on claiming and continuation application practices.⁸⁸ Director Dudas

⁸⁶ See FISCAL YEAR 1998 USPTO ANNUAL REPORT: A PATENT AND TRADEMARK OFFICE REVIEW: IDEAS THAT BECOME VALUABLE INNOVATIONS, *available at* http://www.uspto.gov/web/offices/com/annual/1998/a98r·2.htm (noting that the largest increase in patent applications come from high technology areas).

⁸⁷ The Patent System: Today and Tomorrow: Hearing Before Subcomm. on Intellectual Property of the S. Comm. on the Judiciary, 109th Cong. 10 (Apr. 21, 2005) (Statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office), *available at* http://www.uspto.gov/web/offices/com/speeches/2005apr21.pdf.

⁸⁸ United States Patent and Trademark Office, Department of Commerce, *Changes to Practice* for the Examination of Claims in Patent Applications, Jan. 3, 2006, http://www.uspto.gov/web/offices/com/sol/notices/71fr61.pdf.

The Office is also proposing that if an application contains more than ten independent claims (a rare occurrence), or if the applicant wishes to have initial examination of more than ten representative claims, then the applicant must

proposes that an inventor submitting more than a nominal number of claims must provide the patent examiner with a new "examination support document."⁸⁹

The examination support document will require that the inventor have done a search of the prior art.⁹⁰ The support document will include an information disclosure statement in which the inventor will be obliged to take the most pertinent prior art and apply it to the claims, so it's clear how the invention and the claims relate.⁹¹ The inventor will need to set out the basis on which the invention can be regarded useful, why section 112 support exists in the patent application for the claims, and the underlying basis for patentability over the prior art.

The reception that these proposed rules have received has been far short of an embrace. Resistance to these proposals for inventors forced to operate under today's patent law is unsurprising. The leadership of the Patent Office has made the calculation, driven by its patent application pendency problems, to force patent applicants to file fewer claims in patent applications. Since under today's patent laws, no inventor is about to file an examination support document, the Patent Office calculation is undoubtedly accurate.

What would the situation for inventors be if the three-pillar patent reforms became law, most especially the incentive to obtain a wholly valid patent by providing a safe harbor for fully valid patents against any and all inequitable conduct charges? I would submit that under those conditions, the "examination support document" could and should be made the central feature of all patent examination. In other words, Director Dudas has described the precise tool that is needed for inventors to be able to guide patent examiners through the patent examination process in what should be the paradigm for twenty-first century patent examination look like.

Allow me to move to the concluding portion of this lecture by providing one possible vision for twenty-first century patent examination on the premise that the three-pillar reforms become law. The paradigm could incorporate several new principles.

First of all, the Patent Office should adopt a new mantra for examination: "If you (the inventor) come, they (the Patent Office) will build it. In other words, inventors are always free to come to the Patent Office, present their claims in whatever number or form they desire, and inventors can rest assured that the patent examiners will examine them. The thrust of the new paradigm is antithetical to attempts to limit the workload of the Office by barring the door to an inventor. It is simply and always the inventor's prerogative to define what abundance of claims to protect an invention is needed and the role of the Patent Office to allow the inventor to seek that abundance of claims to protect an invention. As a critical corollary, the

provide an examination support document that covers all of the independent claims and the dependent claims designated for initial examination.

Id. ⁸⁹ Id.

⁹⁰ The Patent System: Today and Tomorrow Hearing Before Subcomm. on Intellectual Property of the S. Comm. on the Judiciary, 109th Cong. 10 (Apr. 21, 2005) (Statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office), *available at* http://www.uspto.gov/web/offices/com/speeches/2005apr21.pdf.

 $^{^{91}}$ Id.

Patent Office must stop restriction practice. It is a means of deferring examination of claims, needlessly relieving both the inventor and the Patent Office of their responsibility to reach a full and final determination of what in the patent application will mature into enforceable rights.⁹²

Once a patent application publishes at eighteen months, the next principle is to oblige the inventor to file an examination support document for each claim in the application. The model for this statement is precisely what Director Dudas proposed in January of this year and that, under the current "inequitable conduct" law, patent practitioner or inventor today is prepared to do.

Why – once a "valid patent safe harbor" becomes law – should the inventor have the affirmative burden of guiding the patent examiner through the invention and its basis for patentability? Among the several reasons are the tremendous acceleration of the patent examination process, the potential for a higher quality work product by a fully briefed patent examiner, and the decreased likelihood that a successful postgrant challenge to the patent will be needed, much less successful. If inventors expect that patents should have the full attributes of property rights, then the greater certainty in the scope of the valid rights and the greater speed in their establishment are essential predicates. Greater applicant responsibility is the key to preserving the twenty-first century patent system as a property-rights system.

A third principle is further needed to cement the property-rights character of the twenty-first century patent system. Once a patent application has been published, Congress should eliminate all continuing applications for patent, most especially the so-called "continuation-in-part applications" in which new disclosure and broader claims may be introduced. The last decade has seen an explosive growth in the filing of continuing applications by a small subset of inventors and practitioners. The practice has become the opiate of the patent profession, or at least some subset of it. Director Dudas has heard the arguments that inventors cannot live without these applications or that, if a small dose of continuing application practice is permitted, the addiction can be kept in control.

It is not unknown for inventors today to file more than a dozen continuing applications and to issue patent after patent based on a single original patent filing. The process of continuing and patenting and continuing and patenting can continue until the 20-year patent term is finally exhausted. The entire 20-year patent term can be consumed before the public has a full and final understanding of what can be patented based upon that single, original patent filing. This is not how the patent system was ever intended to work.

A fourth principle is for Congress to get rid of the notion that patents have to be granted *unless* the patent examiner can demonstrate that the requirements for patentability have not been met. This should be done by increasing patent examiner accountability in exactly the same manner that there is increased applicant responsibility. Patent examiners should be obligated to produce, as the patent examination work product, a "summary basis of patentability" document. Upon reading the document, the public should have an understanding of why a patent was issued on each of the patent claims that issued. This patent examiner work product can be built from the inventor's examination support document – in other words,

⁹² U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 802.02 (8th ed., 2nd rev. 2004).

patent examination becomes more of a partnership in which patent professionals will guide patent examiners through key aspects of the determination of patentability.

If these changes are made, a fifth principle is to dispense with the adversarial language that is used by patent examiners today. Inventions are no longer patentable unless the patent examiner finds a reason to reject claims; inventions are awarded patents only when patent examiners identify sufficient reasons to permit patents to issue. Patent examiners would no longer need to "reject" claims in patent applications because claims would no longer be presumptive patentable. Instead patent examiners could focus on whether a sufficient basis for issuing the patent had yet been established.

If these principles were to be part of a next-generation of patent reform, what would it mean for the patent profession and for the public? First, today there are some patents where the examination record is very thin and the relevance or significance of the patented technology is unclear. Such situations would rarely exist, if they would exist at all, if both patent applicants and patent examiners had these increased responsibilities.

Because public would more rapidly understand the significance of patented inventions and the basis for their patentability, the number of questionable patents would decline and, hopefully, post-grant oppositions would be fewer. In addition, the fuller and clearer prosecution record will assist the public to understand the true metes and bounds of a patented invention, further reducing the patents in which a post-grant opposition might be sought to clarify a patent's reach.

On the Patent Office website is a graph that demonstrates what might happen to the patent examination system if we do nothing to the existing patent examination paradigm. Between now and 2010, it projects an exponential decay in the ability of the Patent Office to issue patents promptly. In some technology fields, patents won't issue for fifty months to one-hundred months after a patent is sought. At this point, the resulting system is effectively non-functional. The Patent Office does project that by changing the patent examination paradigm, future patent pendency figures would radically differ, plummeting to a few months. According to the Patent Office data, the key change needed to work this near-miracle is instituting examination support documents across the board. This solution is more effective and more sustainable that the ongoing efforts at hiring one-thousand new patent examiners a year for the indefinite future. This solution is far better than limiting the ability of inventors to having all their presented claims examined.

Where are we today in this great adventure at reforming the patent laws? Congress is today taking a close look at making truly historic changes.⁹³ A number of impressive studies of the patent system conclude that patent reforms should include quite radical reforms. However, the needed reforms must focus on the root causes for dissatisfaction with patent quality and civil justice for patent litigants. Going after root causes of dissatisfaction should allow us to leave the effectiveness of the patent system as an incentive to create innovation untouched. It should further set the stage for us to move to a new, twenty-first century paradigm for the examination of patents that would increase both the responsibility of patent applicants and the accountability of patent examiners. Only when all these elements of reform have come together should we be satisfied that we have created a patent system fully

⁹³ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

meeting the needs of inventors for securing valuable property rights, as well as the demands of the public for a patent system that produces quality patents and permits them to be challenged and enforced under rules affording civil justice for all patent litigants.