The Economic Implications of Patent Reform:

The Deficiencies and Costs of Proposals Regarding the Apportionment of Damages, Post-Grant Opposition, and Inequitable Conduct

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S O N E C O N

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Executive Summary

Economists have long recognized that the development and spread of economic innovations are the most powerful factors affecting how fast the U.S. economy grows and how much the incomes of most Americans will rise. Changes in the patent rights that protect the intellectual property embodied in innovations, therefore, can affect U.S. prosperity. Our analysis has found that three provisions of the patent reform legislation now before the U.S. Congress could dampen or discourage innovation with potentially serious consequences for the American economy.

Apportioning Damages: The proposal to change the rules for apportioning damages in cases of patent infringements would likely increase those infringements and slow the pace of innovation.

- Damages would no longer reflect the value of the use made of the invention by the infringer or how much a patent owner has lost as a consequence, but only the "value" of the patent's specific contribution compared to everything that came before.

- By reducing the costs of being caught infringing on someone else's patent rights, the new rules will encourage more infringement, which in turn will dampen investment in innovation.

- The new rules also will likely increase the costs of patent suits by requiring that judges and juries assess the "value" of all aspects of an infringed patent and everything in the same area that came before it.

Post-Grant Opposition: The proposal to replace or supplement the current patent-reexamination process with an adversarial, post-grant opposition system modeled on, and possibly even broader than, the procedures of the European Union (EU) could significantly reduce investments in innovation.

- An adversarial, post-grant opposition system would sharply increase the private costs of adjudicating patents: The current reexamination procedures cost less than $15 million a year, compared to an estimated $1.6 billion a year for a post-grant opposition system modeled after the EU process, with even greater costs if the U.S. adopts the broader system under consideration in the U.S. Senate. The difference - at least $15.8 billion over 10 years - would likely come from resources that U.S. innovators otherwise would devote to developing new technologies, products, and processes;

- A new, post-grant opposition system would almost certainly further dampen U.S. innovation by dramatically increasing investor uncertainties about R&D: Based on the

EU's track record, the odds of a patent being challenged could go up 40-fold (from 0.2 percent of patents issued to 8 percent); and the odds that a patent, once challenged, will be revoked could go up another 3.6 fold (from 9.7 percent of challenged patents to 35.1 percent). Considered together, the likelihood of a patent being challenged and subsequently revoked could be as much as 140 times greater under a post-grant opposition system than under current process.

Inequitable Conduct: The proposal to enshrine in federal patent law the "doctrine of inequitable conduct" now followed by some courts, and possibly even broaden it, also could dampen innovation in the United States. The doctrine holds that any intentional omission or misrepresentation in any part of a patent application will void the entire patent, even when the information in question would not have affected the outcome of the original application.

- Since a patent can be cancelled under this doctrine even if its current owner or licensee has no connection to the "inequitable conduct" committed by the original patent applicant, and that conduct would not have affected the outcome of the application, broad use of the doctrine will increase investor uncertainties about the value of patents which they might finance, buy or license, discouraging the development and spread of economic innovations.

- While allegations of "inequitable conduct" usually fail, its broad availability will encourage those charged with patent infringements to search for any evidence of misrepresentation or omissions years earlier, increasing the cost of patent litigation. As with post-grant opposition, these additional costs will come from resources that firms otherwise could use to develop new technologies, products and processes.

- For the purposes of promoting innovation and an efficient patenting system, the current doctrine of inequitable conduct at a minimum should not become statutory law. Rather, the best outcome would be a reform that either abolishes the doctrine or holds that inequitable conduct will render a patent unenforceable only if the misrepresentation or omission materially affected the outcome of the Patent Office's original grant.

Together, these three proposals would make patents harder to secure, easier to invalidate, and cheaper to infringe. The net effects will reduce the value of patents and the intellectual property they represent, dampening R&D and the consequent pace of innovation in the United States.

The Economic Implications of Patent Reform:

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Robert J. Shapiro and Aparna Mathur

Introduction

The critical role of innovation in the economic path of nations is well-established. Since the trail-blazing work of Nobel laureate Robert Solow in the 1950s and Edward Denison in the 1960s, economists have recognized that 35 percent to 40 percent of America's gains in productivity and incomes during the course of the 20th century can be traced to innovation in its various forms. By most measures, the United States continues to lead other countries in the volume and value of its innovations and scientific discoveries.[2] Moreover, the critical role of strong intellectual property rights in driving the pace and extent of innovation has been validated by not only economic research and theory, but also the experience of the innovators and entrepreneurs who translate new ideas into the products and technologies that raise people's productivity and incomes. Consequently, policymakers should consider carefully proposals that would change the terms of those intellectual property rights, so they can ensure that any changes promote rather than impede innovation in the future.

The current patent reform legislation before the U.S. Congress would make many changes affecting intellectual property rights. While the legislation contains a number of positive features, three of its provisions could set back the pace of American innovation. Our analysis found, first, that the proposed changes in the rules for determining damages in cases of patent infringements would increase the costs of patent litigation while significantly reducing the costs of patent infringements. These results would actually encourage more infringements, which in turn would tend to dampen investment in R&D and slow the pace of innovation. Our analysis found further that the proposal to replace or supplement the current patent-reexamination process with a new "post-grant opposition" procedure also could dampen R&D and inhibit the development of new products and processes, principally by increasing investor uncertainties about patents. In addition, the change would likely entail more than $15.8 billion over 10 years in new costs for innovators, compared to the reexamination process, and with no evidence that litigation rates would ease. Finally, our analysis found that the proposal to statutorily codify certain aspects of the judicial doctrine of "inequitable conduct," called by one federal jurist "an absolute plague on the patent system," could similarly dampen R&D and the pace of innovation by again exacerbating investors' uncertainties about the value of patents. This proposal could also slow technology transfers and licensing with potentially large economic effects, because a

[1] The research for this study received support from the Biotechnology Industry Organization (BIO). The analysis and conclusions are solely those of the authors.

[2] See "The Knowledge Economy: Is the United States Losing its Competitive Edge?", Task Force on American Innovation, 2005, http://www.futureofinnovation.org/PDF/Benchmarks.pdf.

patent revocation under this doctrine is not limited to the specific patent claims that are at issue in the litigation but instead reaches the entire patent and sometimes others closely tied to it.

The Role and Terms of U.S. Patents

Patents confer exclusive rights for a limited period to produce, sell and use an invention deemed truly novel, inventive and useful.[3] The economic justification for patenting is not only to reward innovators by creating strong incentives to invest in coming up with new ideas. Patenting also encourages the development of those ideas into marketable innovations by defining the property rights for the ideas, so that rivals have to pay to use or imitate the idea, while promoting additional progress by publically disclosing the inner workings of the original innovation to any potential rival.[4] The economic value of the patent system depends in part, therefore, on both imposing costs on rival firms for imitating an innovation and enabling rival firms to invent around patented innovations.[5]

Patenting has grown sharply in the last decade. The number of patent applications in the United States doubled from the 1990s to 2006, when it topped 170,000.[6] These applications and the process of evaluating them also have grown more complex, with much of this reflecting the patenting of new software and biotechnologies.[7]

Changes in the patenting process have contributed to these developments. Since the 1980s, a series of administrative, judicial and legislative actions have strengthened the value of U.S. patents and extended their coverage in areas such as computer software and business methods. This strengthening of the patent system, however, has raised new concerns and exacerbated old ones, especially about the granting of patents of allegedly "poor quality," and lengthening delays in the time from application to approval.[8] As the statutory requirements for a

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[3] OECD, *Patents and Innovation: Trends and Policy Challenges*, 2004, www.oecd.org/dataoecd/48/12/24508541.pdf.

[4] Kitch, Edmund W., "The Nature and Function of the Patent System," *Journal of Law and Economics* (October 1977): 265-90; Machlup, Fritz. An Economic Review of the Patent System, Study No. 15 of the Senate Committee of the Judiciary, Washington, U.S. Government Printing Office, 1958.

[5] On the first point, one major study found that "patents raise imitation costs by about forty percentage points for both major and typical new drugs, but about thirty percentage points for major new chemical products and by twenty five percentage points for typical chemical products." Levin, R., A. Klevorick, R. Nelson, and S. Winter, "Appropriating the Returns from Industrial R&D," Working Paper, Cowles Foundation, Yale University, 1988. On the second point, see Gallini, Nancy T. "Patent Policy and Costly Imitation," *Rand Journal of Economics* 23.1 (1992).

[6] www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.pdf.

[7] Allison, J. R. and M. Lemley, "The Growing Complexity of the United States Patent System," *Boston University Law Review* 82.1 (2002): 77-144. For further analysis of this growing complexity, see Eric S. Maurer, Comment, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter* 95 (2001): 1057, 1073 (2001); Kieff, F. Scott, *Property Rights and Property Rules for Commercializing Inventions*, 85.4 (2001). The economic evidence is more ambiguous. *See generally* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173 (1986); National Bureau of Economic Research, R & D, Patents, and Productivity (Zvi Griliches ed., 1984); Richard C. Levin *et al*., Appropriating the Returns from Industrial R&D, *op. cit*.

[8] The fraction of patents granted within two years of application fell from 85 percent in the early 1990s to 70 percent in the late 1990s. See Hall, Bronwyn H., Graham, J.H. Stuart., Dietmar Harhoff and David Mowery, "Prospects for

patentable invention are that it be novel, non-obvious, and useful, "poor-quality" patents are those that violate these standards – for example, an invention that has little novelty but considerable breadth, so its holder can extract undue rents from those using it. Moreover, the growing complexity of both patents and the patenting process has increased uncertainty about the reliability and breadth of a patent's claims, for example over what specific features of a technical advance are claimed and whether these claims will be upheld in subsequent legal proceedings. Such uncertainties may cause patent holders to under-invest in their technologies, discourage investment by potential competitors in competing technologies, and produce costly litigation. According to one recent study, such uncertainties arising from low-quality patents can slow the pace of innovation and investments in the commercialization of new technologies.[9] This uncertainty about the validity or scope of a patent also can discourage "cumulative invention," in which one innovator's efforts build on previous advances.[10] These are valid concerns, although researchers have generally not found empirical evidence that these issues have affected R&D investments.[11]

Nonetheless, two provisions in the current patent reform proposals before the U.S. Congress seek to address the issue of low-quality patents – the proposed new terms for apportioning damages in cases of patent infringement, and the creation of the new post-grant opposition process. We will show that, regardless of the potential impact of these proposals on low-quality patents, these proposals could discourage or slow innovation in the United States by increasing uncertainty about intellectual property rights and raising the attendant costs. Further, the proposal to statutorily codify, and perhaps expand, aspects of the existing judicial doctrine of "inequitable conduct" could well undermine efforts to improve patent quality overall, while dampening R&D, innovation, and technology transfers.

The Apportionment of Damages

One proposal that could impose significant economic costs on innovators and the economy are the changes in the terms for assessing damages from patent infringements. Today, under current case law, courts have discretion to award damages based on a range of factors that affect the patent's market value. The damages are determined in the context of each particular infringement, according to the basic principle that the patent holder should recover the commercial benefit that it would have derived from the patent in the absence of the infringement.. Determining the precise extent of that benefit requires the application of complex rules and an assessment of 15 factors set out in the landmark *Georgia Pacific* case, but a guilty

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Improving U.S. Patent Quality via Post-Grant Opposition," NBER Working Paper 9731, 2003, www.elsa.berkeley.edu/~bhhall/papers/BHH%20IPE%20May03WP.pdf.

[9] Hall *et. al.*, 2003, *op cit.*

[10] Scotchmer, Suzanne, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *The Journal of Economic Perspectives* 5.1 (1991).

[11] See, for example, Walsh, John P., Charlene Cho and Wesley M. Cohen, "View from the Bench: Patent and Material Transfers, *Science* 309. 5743 (2005): 2002-2003.

party generally has to pay the owner of an infringed patent damages based on profits lost due to the infringement or, at a minimum, a reasonable royalty for the use made of the invention.[12]

The proposals under consideration by the U.S. Congress would create a new, complicated procedure and standard for determining reasonable royalty damages as the default approach for many cases: Courts would have to conduct an analysis "to ensure that a reasonable royalty is applied only to that economic value properly attributable to the patentee's specific contribution over the prior art," and not to the value of the invention as a whole. This change would mean that, before assessing damages, judges and juries would have to determine the economic value of all of the prior art for an innovation, whether or not they are patented, and the separate value of certain other elements of the product or technology, contained within the asserted patent claims.[13] Thus, adopting this new rule would require that judges and juries in patent cases consider massive additional volumes of data and information, a burden that alone could add weeks or months to most trials and to many appeals, imposing significant new costs on innovators and the courts.[14] Some analysts note that courts already have to assess the patent's contribution over prior art (as part of the "validity" phase of the trial), but that technical analysis of a patent's claims over prior art is very different from an economic analysis of the independent value of those elements. Using prior art as the reference for assessing damages from an infringement also would effectively base that assessment on the value of an invention when its patent application was first filed, rather than when it was actually infringed.

In almost all cases, the proposed changes would produce residual royalties far less than those provided for under current law and often inadequate to compensate the patent holder for the use made of the invention. This approach could have less detrimental effects in software and other areas of IT, where many innovations are incremental and relatively simple to separate from a larger product. But it would be very difficult and potentially damaging in biomedical areas, for instance, where the contribution of a particular patented element is highly complicated and its significance apart from the whole is often not well understood, let alone possible to separately value.

Beyond these considerations, the rigid approach of the proposed new apportionment rules would set aside certain basic economic aspects of any infringement. For example, in assessing damages based not on the market value of the invention but on only certain aspects of it compared to whatever came before it, the new rules ignore the basic economics of competition, in which the sale of a product in a competitive environment often depends on its innovative aspect. There are many cases in which a discrete, novel part of a product accounts for a disproportionate share of its total sales value. In medical devices, for example, the development of a "rapid exchange" capability for angioplasty balloons shifted a large share of the market for entire angioplasty systems to the new product.[15] An infringement of that patent would cost the developer the value of the sales of those entire systems, not simply the "separate" value of the

[12] *Georgia-Pacific Corp. v. U.S. Plywood Corp*., 243 F. Supp. 500, 518 (S.D.N.Y. 1965); Bensen, Eric E., "Apportionment of Lost Profits in Contemporary Patent Damages Cases," *Virginia Journal of Law and Technology* 10.8 (2005).
[13] www.patentlyo.com/patent/2007/05/patent_reform_2_1.html.
[14] www.capwiz.com/bio/issues/alert/?alertid=10320341.
[15] www.nvca.org/pdf/House-SB-Patent-testimony.pdf.

rapid exchange technology. When infringements of patent rights occur, the first question in assessing damages should be what is the invention's value in the marketplace. Moreover, under the proposed changes, if an improvement is deemed to have no value independent of the entire product, the legislative proposals could render the patent effectively irrelevant. The end result is that it will become less expensive to infringe on patents and be caught doing so, which will make infringement just another business decision for many companies. These new rules also could encourage infringers and perhaps even existing licensees to reject negotiated, market-based royalties in favor of pursuing a jury trial, increasing the incidence of litigation and the attendant costs.[16] Ultimately, rules that reduce the cost to infringers will reduce the value of patents subject to such infringements, which in turn could well reduce investments in the R&D that produce innovations.

Post-Grant Opposition versus Post-Grant Reexamination

The United States and the European Union both have procedures by which outside parties can challenge the validity of granted patents. The patent reforms currently under consideration would supplement or replace the current U.S. procedures for post-grant reexamination with an expanded version of the EU process of post-grant opposition. The current U.S. reexamination process, enacted alongside the 1980 Bayh-Dole Act, permits a patent owner or any third party to request that the U.S. Patent and Trademark Office (PTO) reconsider the grounds on which it issued a particular patent. The request must be based on previously undisclosed or unconsidered "prior art,"[17] contained in older patents or printed publications that predate the patented invention that is the subject of a reexamination. If the patent examiner finds a "substantial new question of patentability," the patent is reexamined with no presumption for or against its validity. A reexamination may result in cancellation of all or some of the claims in the patent, or the confirmation of all or some of the claims.[18]

The Bayh-Dole Act created an "*ex parte*" reexamination system, whereby any outside party can submit prior art patents or printed publications challenging a patent's validity and request a reexamination, but with very limited participation in the process. These procedures were designed to allow the PTO to correct errors, create an alternative to litigation in at least some cases, and provide an inexpensive and expert resource if litigation does occur.[19] In 1999, Congress also enacted an *"inter partes"* reexamination procedure that permits the third parties who initiate the process to also submit written briefs and participate in appeals, again to encourage the use of reexamination as an alternative to litigation (these legislative changes were originally entitled, the "Patent Litigation Reduction Act"). The proposed changes now under consideration in the U.S. Senate would replace the *inter partes* reexamination process with a broad and open-ended post-grant opposition system while leaving the *ex parte* process in place,

[16] www.techliberation.com/archives/042507.php.
[17] "Prior art" is a legal term that refers to the body of preexisting publicly-available technical knowledge that has a bearing on the patentability of an invention. Prior art can exist in written form, such as earlier patents, patent applications, or publications, but also in unwritten form, such as products that were on sale, or publicly used, or already known by others in the U.S.
[18] www.ncjolt.org/content/view/36/62/1/1/.
[19] Baughman, Steven J., "Reexamining Reexaminations: A Fresh Look at the *Ex Parte* and *Inter Partes* Mechanisms for Reviewing Issued Patents," *Bloomberg Corporate Law Journal* 2.1 (2007).

allowing challengers to request both reexamination and, if that fails, a post-grant opposition hearing. A bill that passed the U.S. House of Representatives in September 2007 would keep but modify the existing *ex parte* and *inter partes* reexamination system, and add a European style post-grant opposition process available for challengers in the first year after a patent is granted.

PTO data show that the vast majority of reexamination requests are granted–92 percent of *ex parte* reexamination requests and 96 percent of *inter partes* requests. Some 26 percent of the *ex parte* proceedings end in confirmation of all of the patent's original claims, 10 percent result in the cancellation of all claims, and the remaining two-thirds produce partial confirmation of the patent's validity. The *inter partes* proceedings, however, are little used: Since the process was implemented in December 2000, the PTO has received only 308 *inter partes* requests over a period in which it granted more than 1.4 million patents.[20]

While the reexamination system sometimes has been criticized for not providing a real alternative to expensive litigation, because the permitted basis for a reexamination is limited to issues based on prior art patents or printed publications,[21] it still attracts those who wish to claim directly that a patent is invalid, because it is easier to prevail in a reexamination proceeding than in litigation. In a court proceeding, as compared to a reexamination, the challenged patent is "born valid," which means it has a presumption of validity. Further, in court, a challenger has to provide "clear and convincing" evidence that the patent is invalid, rather than a "preponderance of proof."

The opposition procedure in the European Union is a post-grant, adversarial, *inter partes* administrative procedure.[22] Any person or company can file an opposition challenge with the European Patent Office (EPO) within nine months of the grant stating the extent to which the patent is opposed, the grounds for the opposition, and providing relevant facts.[23] The average

[20] One theory offered for such low usage is burdensome estoppels. When a reexamination is complete, the third party requester is estopped from pursuing any civil action regarding the invalidity of any claim determined valid under reexamination on grounds which the third party has actually raised or could have raised during the reexamination. Furthermore, once a decision has been reached in an *inter partes* reexamination or in a district court regarding the validity of a particular claim, neither that party nor its privies can thereafter request an *inter partes* reexamination on the basis of issues which the third party or its privies raised or could have raised. This estoppel does not prevent an assertion of invalidity based on newly discovered prior art. See Baughman, *Ibid.*

[21] The limitation to preexisting patents and printed publications introduces two constraints: First, it makes the reexamination proceeding less useful in technology areas where preexisting technological knowledge exists in other than written form (such as articles that were in public use, software that was on sale, or an invention that was already known by others), and second, it limits the proceeding, for practical purposes, to basic questions of the patent's novelty or obviousness, excluding other legal theories of invalidity that could otherwise be raised in district court.

[22] In Europe, patent protection can be obtained by filing national applications at the respective national patent offices or by one patent application at the European Patent Office. EPO patent grants are issued for inventions that are deemed novel, that mark an inventive step, and are industrially applicable. After an EPO application is filed, the Hague EPO office produces a "search report" for the applicant describing the state of prior art regarded as relevant, including a list of references to prior patents and/or non-patent sources. Applicants are not required to supply a full list of prior art Within six months of the publication of the search report in the EPO Bulletin, applicants must request an examination of their application. See Michel, J. and B. Bettels, "Patent citation analysis – a closer look at the basic input data from patent research reports." *Scientometrics* 51.1 (2001): 181-201; and Hall, Bronwyn H., Graham, J.H. Stuart, Dietmar Harhoff and David Mowery, "Prospects for Improving U.S. Patent Quality via Post-Grant Opposition," NBER Working Paper 9731, 2003.

[23] http://www.law.washington.edu/CASRIP/Newsletter/Vol4/newsv4i2eu1.html.

duration of these challenges is three years, but the costs are relatively low for an adversarial proceeding: The filing fee is 613 Euros; and patent attorney fees are strictly regulated at 15,000 to 25,000 Euros for each party. Regular lawsuits challenging patents in the EU, however, are more costly, ranging from 50,000 to 500,000 Euros. Moreover, and critically important to the current debate over this proposal, researchers have found no substantial evidence that the EU's opposition mechanism reduces patent litigation or its costs.[24]

The reexamination and opposition processes are similar in some respects. In both cases, any third party can ask the patent office to reconsider the grounds on which a patent was issued originally. In a U.S. reexamination, the challenger has to provide a relevant prior art patent or printed publication which could call into question the invention's patentability; and the PTO has to find a "substantial new question of patentability" to proceed. Challengers in the E.U. can similarly offer evidence that the invention did not meet the threshold for patentability of novelty and representing an inventive step; but unlike the U.S. reexamination system, such challenges need not be limited to preexisting patents or printed publications, and the range of legal theories for invalidating a patent is broader than under U.S. reexamination. One point of important contrast is the role of the third-party challenger and the original examiner. Under a reexamination, the challenger has little role in the proceedings, with most communications occurring between the patent owner and the PTO, and the process is usually conducted by the original examiner. Under an EU opposition, the challenger can bring in expert witnesses, submit briefs and new experimental data, and request that deadlines be extended; and the proceedings are conducted by a three-person chamber that may include the original examiner but not in the capacity of a chairperson. Further, once an opposition proceeding begins, the EPO can pursue the case on its own even if the opposition has been withdrawn, which in such cases precludes "out of court" settlements.

The data show clearly that the reexamination process in the United States imposes lower direct costs on the patent system than Europe's opposition system: About 0.2 percent of U.S. patents are subject to reexaminations, and those reexaminations cost $10,000 to $100,000, or an average of $55,000 each; that compares to 8 percent of European patents that are subject to opposition proceedings, at a cost of 15,000 to 25,000 Euros for each side.[25] Some analysts argue that the low number of reexaminations creates social costs by allowing patents of low quality to go unchallenged, and low-quality patents can discourage innovation by leaving other innovators uncertain about their scope. If a new opposition system in the U.S. draws challenges on the level of Europe, however, the higher rates of challenge would increase the uncertainties associated with patent grants.[26] In fact, U.S. rates of opposition challenges would likely be even higher than the EU rates, because compared to the EU system, the proposed changes here would expand the opportunity for challenges to the entire lifetime of the patent and not limit them to the first nine months following a patent's grant.

Moreover, the current U.S. system of reexaminations produces fewer patent revocations than the European opposition system: Under both systems, roughly 23 percent of the challenged

[24] Hall *et. al.*, 2003, *op. cit.*
[25] *Ibid.*
[26] Zandy, Katherine, "Too Much, Too Little or Just Right? A Goldilocks Approach to Patent Reexamination Reform," *NYU Annual Survey of American Law* 61 (2006).

patents are upheld without change; but Europe's opposition proceedings conclude with about one-third revoked and one-third amended, while U.S. reexaminations end with about 10 percent revoked and 66 percent amended.[27] (See Table 1, below.) One reason for this could be the relative rigor of the American patent process, which requires applicants to disclose all information of which they are aware that could be material to the invention's patentability;[28] while another factor may be the more limited basis on which a patent can be challenged through the reexamination process. In any event, the lower rates of revocation in the U.S. should encourage higher levels of R&D, by producing less uncertainty about investments that might produce patents ultimately held to be invalid. While other factors contribute more to determining national R&D commitments, the United States does invest at higher rates in this area than most other countries: From 1996 to 2003, annual R&D spending averaged 2.7 percent of GDP in the United States, compared to 2.4 percent in Germany, 2.2 percent in France, and 1.9 percent in the United Kingdom and across the European Monetary Union.[29] These advantages could diminish if a U.S. opposition system increases the incidence of revocations.

Table 1. Outcomes of Opposition (EU) and Reexamination (US) Proceedings, 1980-2000[30]

Outcome	Oppositions		Reexaminations	
	Number	*Share*	*Number*	*Share*
No Change	5,590	22.4%	716	23.9%
Patent Amended	6,466	33.0%	1,993	66.4%
Patent Revoked	6.655	35.1%	291	9.7%
Closed / No Outcome	1,793	9.5%	0	0.0%
Total	20,464	100.0%	3,000	100.0%

While EPO opposition proceedings are less expensive at 15,000 to 25,000 Euros each than U.S. reexamination proceedings at $10,000 to $100,000 each, the main reason is strict regulation of attorney fees for EU opposition proceedings. Moreover, the role of lawyers in U.S. reexaminations is very limited, while U.S. opposition proceedings would be adversarial and involve much more preparation and attorney involvement. To approximate the likely cost of an opposition proceeding in the United States, we apply the ratio of patent litigation costs to opposition proceeding costs in Europe, and then derive a corresponding value for the U.S. In Europe, patent litigation costs are 13 to 14 times those of a patent opposition, so that U.S. average litigation costs of a little over $2 million suggest that opposition proceedings in the U.S. will cost an average of about $150,000. Those costs would be nearly triple the current, average cost of $55,000 for reexamination; and one study has estimated that the cost of opposition proceedings in the U.S. could reach, on average, as much as $500,000.[31] Furthermore, recent surveys by the American Intellectual Property Law Association estimate that the average costs of

[27] Hall *et. al*, 2003, *op. cit.*

[28] Michel, J. and B. Bettels, "Patent citation analysis – a closer look at the basic input data from patent research reports." *Scientometrics* 51: 181-201, 2001. In 1999, for example, applications to the U.S. PTO cited three times as many references as applications to the EPO.

[29] World Bank, World Development Indicators, 2008,

[30] Hall *et. al.,* 2003, *op. cit.*

[31] Levin, Richard and Jonathan Levin, "Patent Oppositions," Stanford Law and Economics Olin Working Paper No. 245; Yale Law & Economics Research Paper No. 283, 2002.

patent litigations have been rising.[32] Like patent litigation, the costs of an opposition proceeding will almost certainly rise over time as well, especially since the opposition system functions very much like a litigation proceeding with attorneys and courts. Both supplementing and supplanting reexaminations with opposition proceedings (respectively, for the current *ex partes* and *inter partes* procedures) also would lengthen the process, since oppositions in Europe take an average of three-to-five years compared to two years for a typical U.S. reexamination, increasing both costs and investor uncertainties. For all of these reasons, our $150,000 estimate of the cost of oppositions in the U.S. should be considered very conservative.

It is worth noting here that Japan, along with China and Taiwan, once offered both a reexamination type of proceeding as well as an opposition process. All three countries have abolished their opposition systems in favor of invalidation proceedings, concluding that the dual systems permitted undue harassment of patentees, increased uncertainties around patent rights, and claimed inordinate patent office resources.[33]

Creating a new, costly opposition procedure to challenge the validity of an issued patent on a broad range of grounds throughout its life–going beyond even the EU model–also would increase the risks for angel and venture capital investors, which in turn will reduce their investments in innovation and hamper patent holders' ability to make business plans. With higher uncertainties, patents also would become more difficult to divide, combine and license in efficient ways. All of these outcomes would be most prevalent in cases of particularly valuable patents and cumulative inventions, which today are more likely to attract patent challenges.[34] And as noted earlier, there is no statistical evidence that a new opposition process would reduce litigation rates.[35]

The costs of a new opposition proceeding in the United States

While it not possible to measure directly the impact of an opposition system on rates of invention and the quality of innovations, our approach here follows that of other studies in estimating the direct costs of an opposition proceeding, relative to the benefits in avoided litigation costs, compared to the direct costs and comparable benefits of the current reexamination arrangements.[36] One study, for example, posits that an opposition system could reduce litigation by making patent challenges easier for third parties, thus increasing the likelihood of low-quality patents being challenged and revoked or amended.[37] This reasoning cannot explain why the patent litigation rate in the EU, with its opposition system, is generally comparable to the United States. Moreover, the same analysis fails to compare the net benefits it attributes to an opposition system with the net benefits under reexaminations, a serious omission

[32] www.lawyersweekly.com.au/articles/Making-it-in-US-patent-litigation_z69437.htm.
[33] www.ncjolt.org/content/view/36/62/1/1/.
[34] Allison, J. R, *et. al*., 2003, *op. cit*.; Johnson, D. K. and David Popp, "Forced out of the Closet: The Impact of the American Inventors Protection Act on the Timing of Disclosure," NBER Working Paper No. 8374, 2001; and Lanjouw, J. O., and M. Schankerman, "Characteristics of Patent Litigation: A Window on Competition," *Rand Journal of Economics* 32.1 (2001).
[35] Hall *et. al*., 2003, *op cit*.
[36] Others adopting this approach include Hall, *et. al*, 2003, *op. cit*; and Levin *et. al*., 2002, *op. cit*.
[37] Hall *et. al*., 2003, *op cit*.

given that 8.0 percent of EU patents face challenge under the opposition system compared to 0.2 percent of U.S. patents challenged in the reexamination proceeding.

Here, we approach this question by comparing the net costs under reexamination with those under an opposition system, assuming that U.S. opposition and litigation rates followed those in the EU. (As suggested earlier, the rate could well be even higher in the U.S., because one current proposal would create a system with a broader scope and longer window for opposition challenges, compared to the EU's system.) Setting aside for now the impact on litigation, it should be clear at once from the opposition system's much higher rates of challenge that its total costs will greatly exceed those of a reexamination regime. Reexaminations cost on average $55,000, and their incidence in the U.S. is 0.002 (0.2 percent), producing a cost per-patent issued of $110 ($55,000 x 0.002). Our analysis suggests that opposition proceedings will cost on average $150,000, another has estimated the cost at $500,000.[38] Using the conservative opposition incidence rates from the EU of 0.08 (8 percent), the cost per-patent issued in the United States would be $12,000 to $40,000 ($150,000 x 0.08 and $500,000 x 0.08). On that basis, replacing reexaminations with an opposition process would increase costs by $11,890 to $39,890 per-patent issued. In 2006, the U.S. PTO issued 96,174 utility patents to U.S. residents. This suggests that the direct additional costs of an opposition system, compared to reexamination, would be between $1.14 billion and $3.84 billion per-year.[39] (If we use all utility patents issued by the PTO in 2006, 162,509, the direct annual costs of an opposition system would be $1.9 billion to $6.5 billion greater than those of the current reexamination system.[40])

To justify such a large cost increase, the opposition system would have to sharply reduce litigation costs. The most direct way to calculate this is to compare the difference in litigation rates under the two systems. If the higher rate of oppositions substantially reduces litigation rates, the cost saving would be large since patent litigation in the U.S. costs an average of $2 million per case. However, there is no reliable evidence suggesting that this would occur. The one study that set out to evaluate the impact of opposition proceedings on litigation rates concluded that the data could not support a claim that patent litigation rates are lower in the EU than in the U.S.[41]

We also can think through the cost issue by calculating a range of estimates associated with hypothetical reductions in the patent litigation rate, and ask ourselves if they are plausible. For example, if an opposition system reduces U.S. patent litigation rates from the current level of 1.9 percent to 1.8 percent, or by 0.001, and each litigation case costs $2 million, the benefits would be $2,000 per-patent issued or about $192 million, or about 17 percent of the additional cost of the opposition system. To offset even the lower estimate of those additional costs, $1.14 billion per-year, the new system would have to reduce U.S. patent litigation rates by 0.006 to 1.3

[38] Respectively, Hall *et. al*., 2003, *op. cit*; and Levin *et. al*, 2002, *op cit.*
[39] www.uspto.gov/web/offices/com/annual/2006/50308_table8.html.
[40] www.uspto.gov/web/offices/com/annual/2006/50306_table6.html.
[41] Hall *et. al.*, 2003, *op cit.* See also, Stauder, D., P. von Rospatt, and M. von Rospatt, "Protection transfrontalière des brevets europeéns." Revue Internationals de Droit Economique 1 (1999): 119-133; Stauder, D., "Aspekte der Durchsetzung gewerblicher Schutzrechte: Fachkundiger Richter, schnelles Verfahren und europaweites Verletzungsgebot," in: J. Straus (ed.) Aktuelle Herausforderungen des geistigen Eigentums. Köln, 1996; and Cremers, K., "Determinants of Patent Litigation in Germany," paper presented at the ZEW Workshop on the Empirical Economics of Innovation and Patenting, Mannheim, Germany, 14-15 March 2003.

percent, or nearly one-third, an outcome highly unlikely in the litigious United States. And even if oppositions reduced patent litigation rates by 80 percent, from 1.9 percent to 0.38 percent, the savings would be less than the high-end estimate of the new system's additional annual costs of $3.84 billion. No study or analysis has ever claimed that an opposition system could reduce U.S. patent litigation rates by even the lower end of this range, much less by 80 percent.

Finally, we estimate the net, additional costs over the next 10 years if an opposition system were enacted. First, we project the increase in the number of utility patents granted to U.S. residents for the years 2009-2018, assuming an opposition system were enacted in 2008 and projecting new patents from their past levels (1990-2006) using a growth or exponential trend.[42] We adopt here the conservative estimate of $150,000 for the average cost of an opposition proceeding, and project the total costs using the EU's opposition rate of 8 percent of all patents. We also estimate these costs using a higher opposition rate of 10 percent. In addition to the broader scope and longer window for challenges under the current proposals, two additional factors suggest that an opposition system in the United States would attract more challenges than in the EU: In contrast to the EU, the fees of U.S. lawyers are unregulated, and the losing party does not have to pay a portion of the winner's legal fees.[43] For both reasons, the incentives to press opposition cases could be higher in the United States than in the EU.

This analysis shows that adopting an opposition system in the United States would increase the costs of patent validation, compared to our current reexamination approach, by nearly $16 billion over the next 10 years, even using the most conservative estimate of the average cost of an opposition proceeding (Table 2). The higher estimate of the cost of a typical proceeding would bring the additional 10-year costs to more than $50 billion.

Table 2: Estimated Costs of Oppositions and Reexaminations, 2009-2018

(Opposition Rate of 8% and Cost of $150,000; Reexamination Rate of 0.2% and Cost of $55,000)

Year	Number of Patents	Total Cost of Oppositions	Total Cost of Reexaminations	Net Additional Costs
2009	109,391	$1,312,694,604	$12,033,010	$1,300,661,594
2010	114,105	$1,369,261,131	$12,551,550	$1,356,709,581
2011	119,022	$1,428,265,218	$13,092,420	$1,415,172,798
2012	124,151	$1,489,811,904	$13,656,610	$1,476,155,294
2013	129,501	$1,554,010,755	$14,245,110	$1,539,765,645
2014	135,081	$1,620,976,057	$14,858,910	$1,606,117,147
2015	140,902	$1,690,827,023	$15,499,220	$1,675,327,803
2016	146,974	$1,763,688,001	$16,167,140	$1,747,520,861
2017	153,307	$1,839,688,697	$16,863,770	$1,822,824,927
2018	159,914	$1,918,964,410	$17,590,540	$1,901,373,870
2009-2018		**$15,988,187,800**	**$146,558,280**	**$15,841,629,520**

[42] http://www.uspto.gov/web/patents/stats.htm. We exclude design and plant patents, since the PTO does not distinguish in those cases patent holders of U.S. or foreign origin. If these patents were included, the number of issued patents would be even higher.

[43] www.sixwise.com/newsletters/06/10/05/how_many_lawsuits_are_there_in_the_us__amp_what_are_they_for_an_amazing_overview.htm.

Moreover, using the low-end, $150,000 estimate of the per-proceeding cost and a 10 percent estimate for the rate of oppositions, the analysis finds that adopting an opposition system would increase the costs of patent validation by about $20 billion over the next decade (Table 3). The new system could also produce new economic benefits by weeding out more low-quality patents; but there is no evidence that such benefits would approach these projected additional costs.

Table 3: Estimated Costs of Oppositions and Reexaminations, 2009-2018
(Opposition Rate of 10% and Cost of $150,000; Reexamination Rate of 0.2% and Cost of $55,000)

Year	Number of Patents	Total Cost of Oppositions	Total Cost of Reexaminations	Net Additional Costs
2009	109,391	$1,640,868,255	$12,033,010	$1,628,835,245
2010	114,105	$1,711,576,414	$12,551,550	$1,699,024,864
2011	119,022	$1,785,331,523	$13,092,420	$1,772,239,103
2012	124,151	$1,862,264,880	$13,656,610	$1,848,608,270
2013	129,501	$1,942,513,444	$14,245,110	$1,928,268,334
2014	135,081	$2,026,220,072	$14,858,910	$2,011,361,162
2015	140,902	$2,113,533,779	$15,499,220	$2,098,034,559
2016	146,974	$2,204,610,001	$16,167,140	$2,188,442,861
2017	153,307	$2,299,610,872	$16,863,770	$2,282,747,102
2018	159,914	$2,398,705,512	$17,590,540	$2,381,114,972
2009-2018	**--**	**$19,985,234,752**	**$146,558,280**	**$19,838,676,472**

The impact of greater uncertainty on R&D investment

The sharp increase in patent challenges under an opposition system would entail other costs as well: By creating more uncertainty among investors about the long-term value of the patents produced by their R&D investments, it could reduce those investments and the pace of innovation. To analyze this potential dynamic, we create a simple model to study the impact on investment of a high opposition rate and more uncertainty among firms about their ability to defend their patents. The model divides time into two periods: In the first period, firms invest in R&D for innovative products and then produce those products; in the second period, the firms realize the revenues from those products. Under the opposition system, uncertainties increase about the revenues collected in period two. Estimating the returns on the R&D investments requires an assumption about the probabilities that the patent will be challenged and that it will be found valid or invalid. The mathematics are presented in Appendix 1, and the results can be stated plainly here: Uncertainty arising from patent challenges will lower the expected return on R&D investments and thus reduce those investments; and the higher the probability of the patent being opposed and subsequently revoked, the lower the expected return and the lower the investment.

Based on the EU experience, the probability of a challenge under an opposition system is 8 percent, and the probability that a challenged patent will be revoked is 35 percent: Together, there is a 2.8 percent probability that the investment that produces a patent will subsequently be lost through opposition proceedings. This compares to the current reexamination system, in

which the probability of challenge is 0.2 percent and the probability that a challenged patent will be revoked is 10 percent: Together, the probability of a total loss is 0.02 percent. The enactment of opposition system would increase these uncertainties 140 times (2.8/0.02), a result that suggests that an opposition regime could significantly reduce investment in R&D and slow the pace of innovation.

The Doctrine of Inequitable Conduct

The doctrine of inequitable conduct in patent law, originally a judicially-created defense to charges of patent infringement, holds that any patent secured by "unclean hands," by omitting or misrepresenting critical information, is unenforceable.[44] The doctrine has been widely and fairly criticized for holding that inequitable conduct regarding one part or claim in a patent should make the entire patent unenforceable,[45] and in some cases can affect and render unenforceable other patents merely related to the original one.[46]

The standards for determining what constitutes inequitable conduct are based on PTO Rule 56, "Duty to disclose information material to patentability," which establishes a duty to not intentionally fail to disclose to the PTO any information material to a patent application. To establish inequitable conduct, a party must prove both that some undisclosed information was material to the patent and that the lack of disclosure was intentional.[47] In practice, inequitable conduct involves either omissions of material information or misrepresentation of them. An omission or misrepresentation of material information is considered intentional if the party deliberately deceived or misled the PTO; but as with all subjective standards, circumstantial evidence can be used to prove the intent, including what constitutes "material information."[48]

While the doctrine has been applied with fairly limited frequency, the potential impact of its application shapes behavior in many cases. The critical issue is that the sanction is not limited to a particular claim that was misrepresented or the prior art that was withheld. Rather, one act of inequitable conduct in one aspect of a large and complex patent application can render all of the patent's claims unenforceable as well as other patents in the same family, and even if the

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[44] See *Consol. Aluminum Corp. v. Foseco Int'l Ltd.* 90, F. 2.d 804, 812 (Fed. Circuit 1990).
[45] *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc*., 863 F.2d 867, 877 (Fed. Circuit 1988).
[46] See *Pharmacia Corp. v. Par Pharm*., 417 F.3d 1369, 1374-75 (Fed. Circuit 2005)
[47] Information is considered material under Rule 56 if "(1) it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." Information that falls within this standard, but would be cumulative with information already provided to the PTO, is not considered material. Courts, however, are not bound by this definition of materiality, and in fact apply various standards for assessing materiality, including a test that examines simply whether the information withheld or misrepresented would have been "important" to a reasonable examiner in issuing a patent. The PTO itself rejected a similar test when it revised its standard in 1992, due to concerns that such a test is insufficiently objective or rigorous in linking the misconduct to invalidity of the patent. The current proposal under consideration in the U.S. Senate would codify this low, subjective standard for materiality across the board, while the U.S. House proposal would codify Rule 56's definition with minor changes.
[48] Cotropia, Christopher, "Recent Developments in the Inequitable Conduct Doctrine and their Impact on Patent Quality," 2005, www.ipo.org/AM/Template.cfm?Section=IPO_Annual_Meeting2&Template=/ CM/ ContentDisplay.cfm&ContentID=15882.

information that was withheld or misrepresented would not have affected the outcome of the patent application. Further, this sanction of unenforceability may be applied even against innocent patent owners. In life science technologies, for example, patents often are sold or licensed—sometimes several times—before the technology is fully developed and marketed, and the patent is litigated. Owners or licensees of such patents, after years of product development and marketing efforts involving up to several hundred million dollars, may have to defend the patent against inequitable conduct charges even if they were never involved in the original patent application years earlier.

The breadth of the doctrine of inequitable conduct is so great that it is alleged in a *majority* of patent litigation cases and is commonly thought to be a major factor in rising patent litigation costs. Consider its appeal: If a party can prove inequitable conduct by a patent holder in any aspect of its patent application, the entire patent becomes unenforceable, even if it was otherwise valid and the party had infringed on its legitimate claims. Although these allegations rarely succeed, considerable time and expense are often expended during litigation discovery searching a patent owner's files for potentially deceptive omissions or statements made years before, when the patent was applied for. The U.S. Court of Appeals for the Federal Circuit surveyed these developments and wrote that the unproductive state of inequitable conduct litigation has become "an absolute plague on the patent system."[49] Yet, rather than abolish or reform the inequitable conduct doctrine to reduce its costs on the patent system, the current legislative proposals to codify certain aspects of this doctrine in statutory form could actually extend the reach of this "plague."

Much as with the proposed opposition system, these proposals will discourage innovation by increasing the uncertainties of investors about the value of the patents coming out of their investments. Moreover, they may affect not only the development of new technologies and products, but also their adoption and success through technology transfers and patent licensing. Investors evaluating a patent for in-licensing cannot discover a "deceptive" state of mind in their due diligence. The tremendous damage that an unexpected but successful inequitable conduct attack can cause a licensee, therefore, reduces the value of licensed patents, in some cases sufficiently to preclude licensing.[50] These uncertainties will translate into lower business investment, as the new provision increases patent owners' and investors' uncertainties about the costs and delays associated with potentially being subject to allegations of inequitable conduct.

The doctrine of inequitable conduct also has harmful effects on the efficiency and quality of the overall patent system. Concerns about later being accused of misrepresenting or withholding material information may well chill communications between inventors and patent examiners during the application process. At a time when patent applications are more numerous and complex than ever before, and the Patent Office faces a mounting backlog of unexamined applications, inequitable conduct concerns drive some applicants to volunteer less about their inventions, so as not to be accused later of "misrepresentations." The same concerns also can drive many applicants to submit huge volumes of prior art, to lower the likelihood of later being accused of withholding something material. This is not good for patent examination quality.

[49] www.goliath.ecnext.com/coms2/gi_0199-5743246/The-Inequitable-Conduct-Plague-in.html.
[50] www.capwiz.com/bio/issues/alert/?alertid=10320341.

For the purposes of promoting innovation and an efficient patenting system, the current doctrine of inequitable conduct at a minimum should not become statutory law.[51] Rather, the best outcome would be a reform that either abolishes the doctrine or holds that inequitable conduct will render a patent unenforceable only if the misrepresentation or omission materially affected the outcome of the Patent Office's original grant.

Conclusion

The three legislative proposals considered in this study would undermine the value of long-lived patents, which could seriously undercut investment in R&D and slow the pace and quality of innovation in the United States, especially in patent-intensive industries such as biotechnology and other life science areas. The proposals to change the rules for apportioning damages for patent infringements could substantially reduce the costs of infringing on the patent rights of others, and thereby increase the incidence of those infringements. In so doing, the new rules will reduce the average returns on developing new products and technologies, which in turn will dampen the investments to develop them and the consequent pace of innovation. The changes also would shift much of the legal burden in infringement cases from the infringer to the patent holder, by explicitly prohibiting damages based on the market value of the infringing product or process, unless the patent owner "shows that the patent's specific contribution over the prior art is the predominant basis for market demand for an infringing product or process." The result in many cases may well be that the infringer will pay limited damages and continue the infringement, because under the new rules it could make good business sense. The net effect will be a damage calculation process that is more complex, expensive and time-consuming for the courts, and produces judgments that are cheaper for infringers, than today. These results will inevitably discourage investment, especially in high-cost and high-risk areas of research such as efforts to develop next-generation biologic therapies, treatments and technologies.

The provisions to create a new post-grant opposition process also could discourage innovation. First, it would add billions of dollars in additional costs for all industries that depend on patent rights. In addition, it would increase investor uncertainties about patent rights and so reduce investment in those industries. A new opposition process on the European model—or one even broader—also could become a vehicle for harassing patent owners and a new impediment to their enforcing their patent rights.[52] And if this new procedure produces a comparable rate of challenges in the United States as it has in the EU, it could severely strain the PTO's resources.

Finally, the proposal to enact in statutory form the rules of "inequitable conduct" followed by some courts also would increase uncertainties about the long-term value of patents, and so again dampen investment in the development of new technologies and products. This provision could particularly affect the spread of new technologies by increasing the risks of licensing patents developed by others. This provision also could become a vehicle for harassing patent owners and produce additional burdens on the PTO as patent applicants respond

[51] *Ibid.*
[52] California Healthcare Institute, "Impact of Patent Law Changes on Biomedical Investment and Innovation," 2005, www.chi.org/uploadedFiles/CHI%20Patent%20Law%20changes%20paper.pdf.

defensively to the possibility of an "inequitable conduct" charge years later with enormous volumes of potential prior art.

Each of these three proposals presents challenges for not only biomedical companies,[53] but all innovative enterprises that rely on patent protection. Individually, each produces changes that will make the process of securing patents more complicated and more expensive. Taken together, they represent a dramatic shift that will make patents harder to secure, easier to invalidate, and cheaper to infringe. The net effects will reduce the value of patents and the intellectual property they represent, and dampen investments in vital R&D and the consequent pace of innovation. More generally, the proposed changes would impose substantial costs on the United States with no evidence of any clear quantifiable benefits. While patent reform is needed in many areas, we conclude that these proposals are neither justified nor advisable.

[53] Innovation in biotechnology, perhaps more than any other industry, depends on strong patent rights and protections. More than 325 million people worldwide have used some 155 biotechnology drugs and vaccines, and the development of each of them, on average took a decade or longer and cost $800 million to $1.2 billion. Only 10 to 30 percent of biotech development projects produce useful treatments, and those which do require complex manufacturing systems that take on average five years to construct at a cost of more than $1 billion. And only 30 percent of the treatments that reach patients earn revenues that match or exceed the average R&D costs. Biotechnology companies and their investors can continue to accept these high costs and large risks and uncertainties—and so continue to produce treatments for the most grave and common health problems—only if they can continue to rely on patent laws that enable them to earn returns on their investments.

References

Allison, J. R., M. A. Lemley, K.A. Moore, and R. D. Trunkey, "Valuable Patents," University of Texas at Austin, University of California at Berkeley, and George Mason University: Draft manuscript, 2003.

Allison, J. R., and M. Lemley, "The Growing Complexity of the United States Patent System," *Boston University Law Review* 82.1 (2002): 77-144.

American Intellectual Property Law Association, "Report of Economic Survey," Washington, D.C., 2001.

Arora, Ashok, M. Ceccagnoli and Wesley M. Cohen, "R&D and the Patent Premium," NBER Working Paper No. 9431, 2003.

Barton, J. H., "Reforming the Patent System," *Science* 287 (2000): 1933-1934.

Baughman, Steven J., "Reexamining Reexaminations: A Fresh Look at the *Ex Parte* and *Inter Partes* Mechanisms for Reviewing Issued Patents," *Bloomberg Corporate Law Journal* 2.1 (2007).

Bensen. Eric. E., "Apportionment of Lost Profits in Contemporary Patent Damages Cases," *Virginia Journal of Law and Technology* 10.8 (2005).

Biotechnology Industry Organization, "Biotechnology Industry Facts," http://www.bio.org/speeches/pubs/er/statistics.asp.

Boston Consulting Group, "A Revolution in R&D – the impact of genomics," *BCG Focus,* June 2001.

California Healthcare Institute, "Impact of Patent Law Changes on Biomedical Investment and Innovation," 2005, http://www.chi.org/uploadedFiles/CHI%20Patent%20Law%20changes%20paper.pdf.

Cohen, W.M., R.R. Nelson, and J.P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent or Not", NBER Working Paper 7552, 2002.

Cotropia, Christopher A., "Recent Developments in the Inequitable Conduct Doctrine and their Impact on Patent Quality," 2005, www.ipo.org/AM/Template.cfm?Section=IPO_Annual_Meeting2&Template=/CM/ContentDisplay.cfm&ContentID=15882.

Cremers, K., "Determinants of Patent Litigation in Germany," paper presented at the ZEW Workshop on the Empirical Economics of Innovation and Patenting, Mannheim, Germany, 14-15 March 2003.

DiMasi, Joseph A., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22.2 (2003): 151-185.

Gallini, Nancy T., "The Economics of Patents: Lessons from Recent U.S. Patent Reform," *The Journal of Economic Perspectives* 16.2 (2002): 131-154.

Gallini, Nancy T., "Patent Policy and Costly Imitation," *Rand Journal of Economics* 23.1 (1992): 52-63.

Gilbert, Richard, and Carl Shapiro, "Optimal Patent Length and Breadth," *Rand Journal of Economics* 21.1 (1990): 106-112.

Hall, Bronwyn H., Graham, J.H. Stuart., Dietmar Harhoff, and David Mowery, "Prospects for Improving U.S. Patent Quality via Post-Grant Opposition," NBER Working Paper 9731, 2003, http://elsa.berkeley.edu/~bhhall/papers/BHH%20IPE%20May03WP.pdf.

Hall, B. H., and R. H. Ziedonis, "The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995." *Rand Journal of Economics* 32.1 (2001): 101-128.

Johnson, D.K, and David Popp, "Forced out of the Closet: The Impact of the American Inventors Protection Act on the Timing of Disclosure," NBER Working Paper No. 8374, 2001.

Kieff, F. Scott, "Property Rights and Property Rules for Commercializing Inventions," *Minnesota Law Review* 67.4 (2001).

Kingston, W., "Innovation Needs Patents Reform," *Research Policy* 30.3 (2001): 403-423.

Kitch, Edmund W., "The Nature and Function of the Patent System," *Journal of Law and Economics* 20 (October 1977): 265-90.

Klemperer, P., "How Broad Should the Scope of Patent Protection Be?" *Rand Journal of Economics* 2.1 (1990): 113-130.

Lanjouw, J. O., and M. Schankerman, "Enforcing Patent Rights: An Empirical Study," Brookings Institution and London School of Economics, August 2002.

Lanjouw, J. O., and M. Schankerman, "Characteristics of Patent Litigation: A Window on Competition," *Rand Journal of Economics* 32.1 (2001): 129-151.

Lemley, M. A., and J. R. Allison, "Empirical Evidence on the Validity of Litigated Patents," *American Intellectual Property Law Association Quarterly Journal* 26 (1998): 185.

Lerner, Joshua, "Patenting in the Shadow of Competitors." *Journal of Law and Economics* 38.2 (1995): 463-96.

Levin, Richard C., and Jonathan Levin, "Patent Oppositions," Stanford Law and Economics Olin Working Paper No. 245; Yale Law & Economics Research Paper No. 283; SIEPR Discussion Paper No. 01-29, 2002.

Levin, R., A. Klevorick, R. Nelson, and S. Winter, "Appropriating the Returns from Industrial R&D," Working Paper, Cowles Foundation, Yale University, 1988.

Lunney, G. S., Jr., "e-Obviousness," *Michigan Telecommunications Technology Law Review* 7 (2001): 363-422.

Machlup, Fritz, "An Economic Review of the Patent System," Study No. 15 of the Senate Committee of the Judiciary, Washington, DC: U.S. Government Printing Office, 1958.

Magrab, E. B, "Patent Validity Determinations of the ITC: Should U.S. District Grant Them Preclusive Effect?" *Journal of the Patent & Trademark Office* Society 75 (1993): 127-135.

Mansfield, Edwin, "Patents and Innovation: An Empirical Study," *Management Science* 32 (1986): 173.

Maurer, S. Eric, "Comment, An Economic Justification for a Broad Interpretation of Patentable Subject Matter," *Northwestern University Law Review* 95 (2001): 1057, 1073.

Meador, Daniel J., "The Origin of the Federal Circuit: A Personal Account," *American University Law Review* 41.2 (1992): 581-620.

Merges, R. P., "As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform," *Berkeley High Technology Law Journal* 14 (1999): 577-615.

Merges, R. P., *Patent Law and Policy*, Charlottesville, VA: Michie., 2001.

Michel, J., and B. Bettels, "Patent citation analysis – a closer look at the basic input data from patent research reports." *Scientometrics* 51 (2001): 181-201.

Milken Institute, "Biotechnology Valuations for the 21st Century," April 2002. http://www.dist.maricopa.edu/bwd/biotechpb.pdf.

National Bureau of Economic Research, *R & D, Patents, and Productivity*, Zvi Griliches ed., 1984.

"Patents and Innovation: Trends and Policy Challenges," OECD 2004, http://www.oecd.org/dataoecd/48/12/24508541.pdf.

Pharmaceutical Research and Manufacturers of America, "Why Do Prescription Drugs Cost So Much and Other Questions About Your Medicines,"
http://www.phrma.org/publications/publications/brochure/questions/questions.pdf.

Scotchmer, Suzanne, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *The Journal of Economic Perspectives* 5.1 (1991): 29-41.

Sheehan, J., D. Guellec, and C. Martinez (2003), "Business Patenting and Licensing: Results from the OECD/BIAC Survey", in *Patents Innovation and Economic Performance*, proceedings of the OECD conference on IPR, Innovation and Economic Performance, 28-29 August 2003

Somaya, D., "Patent Litigation in the United States (1970-2000)," Chapter 2 of a Ph.D. Thesis, Haas School of Business, University of California at Berkeley, 2002.

Stauder, D., P. von Rospatt, and M. von Rospatt, "Protection transfrontalière des brevets europeéns." *Revue Internationals de Droit Economique* 1 (1999): 119-133.

Stauder, D., "Aspekte der Durchsetzung gewerblicher Schutzrechte: Fachkundiger Richter, schnelles Verfahren und europaweites Verletzungsgebot," in: J. Straus (ed.) *Aktuelle Herausforderungen des geistigen Eigentums*, Köln, 1996.

Toole, Andrew A. and Dirk Czarnitski, "Patent Protection, Market Uncertainty, and R&D Investment," Working Paper 24, Berkeley Center for Law and Technology, 2006.
http://repositories.cdlib.org/cgi/viewcontent.cgi?article=1025&context=bclt.

"The Knowledge Economy: Is the United States Losing its Competitive Edge?" Report by The Task Force on American Innovation (2005), available at:
http://www.futureofinnovation.org/PDF/Benchmarks.pdf.

Zandy, Katherine M., "Too Much, Too Little or Just Right? A Goldilocks Approach to Patent Reexamination Reform," *NYU Annual Survey of American Law* 61 (2006).

Appendix 1

We assume a two-period model in which firms make decisions about how much to invest in innovative activity when they have patent rights over the innovated product. In particular, firms choose their optimal research and development expenditure to maximize the return from their investment in innovative products, which is given by the difference between revenues, *R(k)*, and costs, *C(k)*. (Note that the level of investment in R&D, *k*, is a function of the quantity of output of innovations, *q*. Hence we should write *k(q)*, but ignore this for ease of notation). Investment and production take place in period 1, and in period 2, the firm realizes revenues from the sale of its product. However, there is uncertainty regarding revenues in the second period, since if the patent is challenged, revenues will be realized only if the patent is found valid.

To estimate the expected return on the investment, we make certain assumptions about the probability that a patent will be challenged, and whether the challenged patent will be found valid or invalid. These probabilities are taken from Hall *et al.* (2003), based on outcomes under the EPO opposition system. The probability that a patent will be opposed ($p_{o)}$ is 8 percent, and the probability that an opposed patent will be revoked (p_r) is 35 percent. The probability that there is no challenge is denoted as p_s. (We assume there is no litigation, otherwise the probability of no challenge will be even lower.) Given these probabilities, the expected profit from the investment can be calculated as follows:

$$Expected(\pi(k)) = p_s * R(k) + p_o * [p_r * (0) + (1 - p_r) * (R(k))] - C(k)$$

$$\frac{d\pi}{dk} = p_s R'(k) + p_o (1 - p_r)(R'(k)) - C'(k)$$

$$\Rightarrow \frac{d\pi}{dk} = R'(k)(p_s + p_o (1 - p_r)) - C'(k)$$

$$\text{To maximize profits, firms set } \frac{d\pi}{dk} = 0$$

$$\Rightarrow R'(k)(p_s + p_o (1 - p_r)) = C'(k)$$

Assume (from Hall et al.)

$$p_o = 0.08$$

$$p_r = 0.35$$

$$p_s = 0.92$$

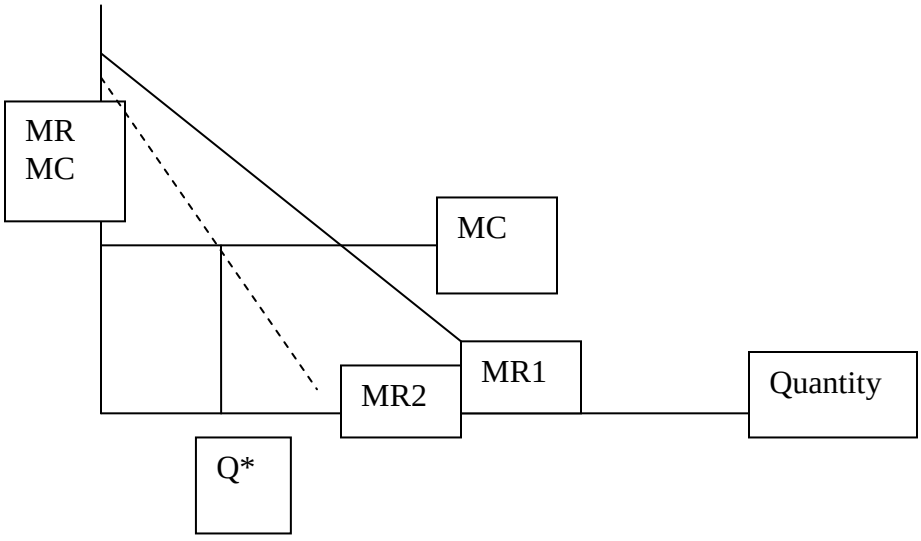
Therefore,

$$0.98MR = MC$$

where MR or marginal revenue is calculated as the derivative of the revenue function w.r.t. *k*, and MC or marginal cost is the derivative of the cost function w.r.t. *k*. Hence firms produce until the point where the additional revenue from producing and selling that product exactly equals the cost of producing it. This situation is depicted in the figure below (we assume constant marginal costs for convenience). In the absence of uncertainty (with $p_s=1$ and all other probabilities at 0),

firms would decide on quantity and therefore R&D investment by equating MC to MR1. However, in the presence of a positive probability of the patent being opposed and revoked, it is as if the firm is forced to operate along MR2, which is below MR1 for all *q* by 2 percent. (Note that we can think of this as a downward shift in the MR curve below the original MR curve, or as an upward shift in the MC curve by 1/0.98 or slightly more than 1 percent). If the demand curve, and therefore the MR curves are fairly elastic, the drop in quantity associated with moving to the lower MR curve could be more than 2 percent. Further, if the elasticity of investment w.r.t. output is also high, the drop in investment could be steep as well. These responses would vary across industries, but in general, the firm will end up innovating less (producing a lower quantity) in each period and subsequently investing less in R&D in each period. Arora et al. (2003) estimates the elasticity of R&D w.r.t. patent premiums i.e. the incremental value of an innovation due to its being patented. We can loosely interpret the premium as the additional return that an innovative product would generate due to its patent protection. The elasticity for most industries tends to be less than 1. For instance, a 10 percent increase in the patent premium would result in a 10 percent increase in R&D in the health care related industries as opposed to 4 to 5 percent in the electronics and semiconductor industries. While the elasticity is less than 1, the impact of a 4 to 5 percent drop is not negligible considering that R&D investments are in the millions of dollars for most industries. This suggests that lower patent protection or higher patent uncertainty could have substantial impacts on R&D investments.

Figure 1-A: Output of Innovative Products Under Uncertainty



Hence the presence of uncertainty due to patent challenges leads to a lower expected return on the investment and causes less investment in research and development than we would expect if firms faced no such uncertainty and were assured of the validity of the patent throughout the life of the patent. The higher the probability of the patent being opposed and subsequently revoked, the lower the expected return and the lower the investment.

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