

**Scientific Expertise in Policymaking:
The Case for Open Review and Patent Reform**

Beth Simone Noveck

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Abstract

The Energy Research Advisory Board, the group of external scientific advisors that provided impartial expert advice to the Secretary of Energy since 1978, was disbanded this May. The Administration, like its predecessors, regularly replaces experts on agency advisory panels with ideologues and political allies. We are at the nadir of a historical progression since World War II away from trust in and use of scientific expertise in policymaking. This shift however, has not been countered with greater public participation. Instead, administrative law and theory have developed a model of the managerial administrative authority. The "expertocratic" agency relies on internal expertise in order to develop policy in the public interest. This is nowhere more the case than in the United States Patent and Trademark Office where the need for secrecy surrounding patent applications has entrenched a conception of the agency as expert. While the first patent examiner, Thomas Jefferson, consulted Joseph Hutchinson, Professor of Chemistry on March 12, 1791 to seek his advice in connection with a patent on an alchemical process, modern patent examiners labor independently under a backlog of 1 million applications with no more than 18-20 hours to decide on the 20 year grant of monopoly rights. The patentability determination, as much if not more so than any regulatory rulemaking by the EPA or FDA, depends upon knowledge of science. Yet examiners lack the requisite knowledge to examine patents adequately. Examiners are prohibited from consulting outside sources, often including the Internet. Still over 90% of applications are granted. This paper argues that the distrust of scientific expertise produces an information deficit that results in poor quality patents. It views patent examination as a case study, illuminating a general problem with administrative policymaking, namely the lack of accountability to and input from scientific experts. The Article puts forward a solution: "open review." Under this model, scientific experts provide input to the agency by means of an online network; that expertise is directly tied to ultimate legal decision-making. Unlike ordinary peer review, called for in the *Information Quality Act*, open review adopts a broader vision of collaborative expertise that cannot be manipulated. By being both more expert and more participatory, it avoids the problems described in the literature on science in policymaking. Unlike other proposals for *ex post* patent reform, open review addresses the core problem of information deficit that cannot be solved by the courts. At this juncture when patent reform is uncertain to move either through Congress or the US Supreme Court, focusing our attention on the role of scientific expertise in agency practice may be our best opportunity, not only to bring about much-needed reform, but to do so in ways that are data-driven and empirically measurable. The United States Patent and Trademark Office agrees with the assessment: it will implement a pilot of open review in 2007.

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Introduction

There is a crisis of patent quality. Vague, overbroad patents lacking in novelty that fail the constitutional mandate of “promoting the progress of science and the useful arts”¹ are being issued. The grant of a high volume of patents (over 350,000 a year) at a staggering rate (upwards of 90% of patent applications are granted) produces increasing uncertainty about their merit. Low quality patents risk litigation and confer the economic rewards of monopoly with little benefit to the public.² In a recent empirical study, “Determinants of Patent Quality: An Empirical Analysis”³ Columbia Professor Bhaven Sampat analyzes

* Assoc. Professor of Law and Director, Institute for Information Law and Policy, New York Law School. Visiting Professor, Annenberg School, University of Pennsylvania. McClatchy Visiting Assoc. Prof., Communications Dep’t., Stanford University. Please note, all footnotes are long form to facilitate subsequent editing.

¹ U.S. Const. art. I, § 8.

² ADAM B. JAFFE AND JOSH LERNER, *INNOVATION AND ITS DISCONTENTS*, 2 (2004) (“Thus, the patent system – intended to foster and protect innovation – is generating waste and uncertainty that hinders and threatens the innovative process.”). See also A PATENT SYSTEM FOR THE 21ST CENTURY 70 (Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, eds., 2004). See also, Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 HOUS. L. REV. 1219, 1227-36 (2004); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1496 (2001); *Editorial: The Problem with Patents*, WALL ST. J., March 29, 2006, at 18.

³ Bhaven Sampat, *Determinants of Patent Quality: An Empirical Analysis* (2006) (unpublished article manuscript available at http://siepr.stanford.edu/programs/SST_Seminars/patentquality_new.pdf_1.pdf).

the dataset of prior art references from 502,687 utility patents issued between January 1, 2001 and December 31, 2003. He finds that “patent examiners have a comparative disadvantage in searching for non-patent prior art and foreign patents, suggesting that all else equal [sic], patents are likely to be of lower quality for technological areas for which most prior art is not embodied in U.S. patents.”⁴ Patent examiners are currently trying to make decisions about a twenty-year⁵ grant of monopoly rights that will shape an industry on the basis of information contained only in the USPTO’s internal databases.⁶ Examiners may not consult the public nor may they talk to experts or, in most cases, even use Google. The information upon which examiners may rely in making a determination is further limited by poor or ambiguous drafting by applicants and the fact that there is no onus upon those applying for a patent to supply adequate information to the examiner. The costs of searching fall to the Patent Office alone.⁷

As James Rumsey remarked in a letter to Thomas Jefferson in 1789, the issuance of patents is “more within the information of a board of academical

⁴ Bhaven Sampat, *Determinants of Patent Quality: An Empirical Analysis 3* (2006) (unpublished article manuscript available at http://siepr.stanford.edu/programs/SST_Seminars/patentquality_new.pdf_1.pdf).

⁵ Patent Act, 35 USC §154(a)(2) (2004) (“Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States...”).

⁶ U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, *MANUAL OF PATENT EXAMINING PROCEDURES* (MPEP) § 902.03(e) (8th ed. 2004) (“The automated search tools on examiners’ desktop computers include the Examiner’s Automated Search Tool (EAST), the Web-Based Examiner Search Tool (WEST), and the Foreign Patent Access System (FPAS).”)

⁷ Lee Petherbridge, *Positive Examination*, 46 *IDEA* 173 (2006) (arguing that we must reduce the information costs of searching imposed upon the Patent Office).

professors, and a previous refusal of a patent would better guard our citizens against harassments by lawsuits.”⁸ Yet today’s patent system replaces expert “academical” input with the centralized and isolated expert-bureaucrat evaluating applications on the basis of a legal fiction, namely from the viewpoint of the “Person Having Ordinary Skill in the Art” (PHOSITA) in whose shoes he is expected to stand.⁹

The information deficit that plagues the Patent Office is a common problem faced by other government agencies as well. There is an institutionalized culture endemic to government that forecloses outside input¹⁰ and produces an information deficit. There is a prevailing distrust of public participation and of scientific expertise, specifically. As Wendy Wagner writes,

⁸ E.C. Walterscheid, *Thomas Jefferson and the Patent Act of 1793*, in 40 *ESSAYS IN HISTORY* (1998) (quoting Letter, James Rumsey to Thomas Jefferson, dated June 6, 1789, in *THE PAPERS OF THOMAS JEFFERSON*, Julian P. Boyd et al., Princeton: Princeton University Press, 1950 at 15:171-2).

⁹ Patent Act, 35 U.S.C. § 103 (2004). See also Rebecca Eisenberg, *Ideas Into Action: Implementing Reform of the Patent System: Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 *BERK. TECH. L.J.* 885, 886 (2004) (“[T]his language seems to call for evaluations of non-obviousness from the perspective of ordinary practitioners who are contemporaries of the inventor in the relevant technological community. It specifies a point in time as of which the obviousness of the invention should be evaluated (‘at the time the invention was made’) and designates the person whose judgment of obviousness should control (‘to a person having ordinary skill in the art to which said subject matter pertains’ or PHOSITA), as well as directing attention to ‘the differences between the subject matter sought to be patented and the prior art.’”)

¹⁰ Beth Simone Noveck, *Electronic Revolution in Rulemaking*, 53 *Emory L.J.* 433, 450 (2004) (“The APA’s spare public consultation provisions have institutionalized the deep-seated belief that the public, especially unorganized individuals or small interest groups, is an irritant - the pea to the agency’s princess - unduly influencing and burdening the expert who alone possesses the knowledge and impartial sangfroid to govern in the public interest.”). See also, Jim Rossi, *Participation Run Amok: The Costs of Mass Participation for Deliberative Agency Decisionmaking*, 92 *Nw. U. L. REV.* 173, 217 (1997) (critiquing value of public participation); See also CORNELIUS KERWIN, *RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY* 178–79 (2 ed. 1999) (describing patterns of participation and contending that, for a variety of reasons, participation in rulemaking is not particularly common or frequent.).

“attempts to incorporate science into environmental regulations have met with failure. Reduced public participation, excessive regulatory delays, and the incomplete and inaccurate incorporation of science have plagued science-based environmental regulation for nearly three decades.”¹¹ The conviction in currency is that outside sources of scientific information compromise agency impartiality and democratic legitimacy. Government agencies have come to rely increasingly on internal expertise to the exclusion of science; science understood in the broad meaning of a certain kind of knowledgeable expert adhering to the professional values dictated by the scientific method. The Patent Office, on which we focus, is but the paradigmatic example of the challenge of making complex decisions without the benefit of adequate information. The solutions we propose, therefore, can apply to the reform of patents as well as to remedy the information deficit at other agencies. Hence the normative analysis should be of interest to intellectual property and administrative law scholars and practitioners alike.

The United States Patent and Trademark Office is the epitome of a dysfunctional conception of expertise in our administrative culture. The earlier need for secrecy surrounding patent applications¹² further entrenched the culture of agency-as-expert and the practice of rejecting scientific input. While the first

¹¹ Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1614 (1995).

¹² Prior to the enactment of the rules on publication in 1999, all applications were kept secret for the duration of prosecution. Patent Act, 35 USC §122 (a) (2004) (providing for confidentiality and secrecy of patent applications); Patent Act, 35 USC §122(b) (2004) (providing for publication at 18 months); see also U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, MANUAL OF PATENT EXAMINING PROCEDURES (MPEP) §1120 (8th ed. 2004) (“Nonprovisional utility and plant applications: are published promptly after eighteen months from the earliest filing date for which application benefit is sought.”).

patent examiner, Thomas Jefferson, consulted Joseph Hutchinson, Professor of Chemistry at the University of Pennsylvania, on March 12, 1791 to seek his advice in connection with a patent on an alchemical process,¹³ this consultative and open vision of patent review subsequently gave way to our modern system of closed patent examination.

Today 4,000 patent examiners¹⁴ labor independently under a backlog approaching 1 million applications¹⁵ with no more than 18-20 hours¹⁶ to review each one. The patentability determination, as much if not more so than any regulatory rulemaking by the EPA, depends upon knowledge of science. Yet examiners lack the requisite information to examine patents adequately: there is

¹³ LEONARD WHITE, *THE FEDERALISTS: A STUDY IN ADMINISTRATIVE HISTORY* 137 (1948) (quoting letter from Thomas Jefferson, dated 12 March 1791 *reprinted in* THE THOMAS JEFFERSON PAPERS 1606-1827 at the Library of Congress, available at http://memory.loc.gov/ammem/collections/jefferson_papers/index.html).

¹⁴ There are currently 4,000+ patent examiners with plans to increase that number to 7,200 in order to address the backlog. See U.S.P.T.O. Draft Strategic Plan 2007-2012, 71 Fed. Reg. 50048 (2006) (In FY 2006, the USPTO plans to hire 1,200 patent professionals, and in years FY 2007 – FY 2012, we plan to hire at least 1,000 a year, for a total of at least 7,200 patent examiner hires in 7 years. This level of hiring is a critical component of the plans to address patent pendency regardless of the time frame for such improvements. Notwithstanding these massive hiring efforts, in the absence of other changes to the current examination system only modest gains in reducing patent pendency are likely to be achieved in the near term. In fact, until these new hires are effectively absorbed into the examination system, average patent pendency will continue to increase.).

¹⁵ At the end of 2005, the number of pending patent applications was 885,002 and rising. See U.S.P.T.O. Draft Strategic Plan 2007-2012, 71 Fed. Reg. 50048 (2006), available at <http://www.uspto.gov/web/offices/com/strat2007/index.htm>.; U.S.P.T.O. Performance and Accountability Report Fiscal Year 2005: Other Accompanying Information: Table 3: Patent Applications Pending Prior To Allowance, available at http://www.uspto.gov/web/offices/com/annual/2005/060403_table3.html.

¹⁶ Kevin Maney, *Examiners Can't Keep Up With Patent Applications*, USA TODAY, June 15, 2005, at http://www.usatoday.com/tech/columnist/kevinmaney/2005-09-20-patent-office_xhtml (quoting John Doll, Commissioner for Patents, USPTO). U.S. GEN. ACCOUNTING OFFICE, H.R. REP. NO. GAO-05-720, *THE USPTO HAS MADE PROGRESS IN HIRING EXAMINERS, BUT CHALLENGES TO RETENTION REMAIN* (2005) (depending on the type of patent and the skill level of the examiner, each examiner is expected to process an average of 87 applications per year at a rate of 19 hours per application). See also, Brenda Sandburg, *Speed Over Substance?*, INTELL. PROP. MAGAZINE (March 1999).

either too little information about prior inventions on file – as in the case of computer software patents – or too much information – as in the case of biotechnology – without the means to sort it. There is no continuing science education at the USPTO and no dialogue with the scientific community.

This paper argues that abjuring input from and accountability¹⁷ to outside scientific expertise produces problems at the Patent Office and across agencies with information quality and information transparency. The central insight is that distrust of science creates an information deficit that, in turn, produces poor quality patents and problematical agency rulemakings. The reluctance to use science translates into undue reliance on centralized structures of expertise and decision making. The distrust of outside expertise is magnified by the concomitant difficulty with engaging experts effectively and efficiently, compounding the informational deficit and turning the patent quality problem into a problem of information access.¹⁸

¹⁷ Temina Madon, *Congress 101: Teaching Scientists The Language Of Policymakers*, 6 BERK. SCI. REV. 43, 44 (Spring 2006) (“Many scientists drawn into the world of policy share a sense that greater numbers of researchers should be involved in the decision-making process. Bruce Alberts, a biochemistry professor at UC San Francisco and former President of the National Academies, has been a strong advocate for the role of science in policy. During his tenure at the Academies he helped establish fellowship programs that bring scientists and engineers to Capitol Hill, with the goal of influencing lawmakers and convincing them to embrace evidence-based approaches in their work.”).

¹⁸ For another perspective on the information problem of patents, see Lee Petherbridge, *Positive Examination*, 46 IDEA 173 (2006) (focusing on the information costs associated with defining the boundaries of a patent and arguing that the failure on the part of the Patent Office to collect sufficient information from applicant is interfering with the ability to efficiently and reproducibly construct a consistent understanding of the boundaries of the patented property. “So viewed, transactions involving questionable patents, and indeed transactions involving all patents, can be productively considered as problems of information costs and information cost allocation.”). See also see Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465 (2004).

The dearth of information, as this Article argues, cannot be solved through judicial review. Contrary to the prevailing theory, “Daubert-izing”¹⁹ agency decision-making and changing the current standard of judicial review (or rather lowering the high degree of deference and lack of review) of agency decisions based on science is too slow, too intermittent and too late in the game to solve the problem. Judicial review comes too late in the process to remedy the informational deficit, especially as judicial review has to await first a 2-5 year review process at the Patent Office itself.²⁰ Judicial review cannot address the question of how policymakers should account for the uncertainty of scientific conclusions and still follow principles of sound science. It does not address how to base decisions on quality information without sacrificing democratic legitimacy.

Other reform proposals that call for *ex post* solutions, such as post-grant administrative review to “gold-plate” important patents, as Lemley, Lichtman and Sampat propose,²¹ still require improved mechanisms for getting at the information necessary to make the patentability determination. Even proposals to change the statutory standards of patent examination and revisit the scope of patentable subject matter or the definition of obviousness do not obviate the need

¹⁹ *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). See Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7 (2003).

²⁰ Joseph Farrell and Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*. 19 BERK. TECH. L. J., 1 (2004).

²¹ Mark A. Lemley, Douglas Lichtman and Bhaven Sampat, *What to Do about Bad Patents?*, 28 REGULATION 10-13 (2005-6) (arguing for post-grant opposition, “a process by which parties other than the applicant would have the opportunity to request and fund a thorough examination of a recently issued patent.”).

to address the grave problem of information deficit. Even where there have been proposals to require applicants to perform more thorough searches, the applicant may lack the incentive and the knowledge to find all the relevant information.

Instead, this Article puts forward a normative proposal for a new reform model²² that might revolutionize the process of patent examination. It is a necessary precursor to all other patent reform proposals because it goes to this central question of the use of scientific information. This proposal for what we shall term “open review” or “open examination” separates scientific from legal decision-making and distributes the former to an external expert community by means of an online network. The scientific community provides informational input about what it knows best and, most important, those contributions are directly tied to the ultimate legal determination. The patent examiner with her deep knowledge of the legal standards of patentability remains the ultimate arbiter. Creating this network of scientific expertise, by means of new technology, would not eliminate the agency official nor would it shield the scientist from political decision-making. This has the potential to remedy the information deficit and improve patent quality.

The crux of this normative proposal is to go beyond more traditional peer review (e.g. as called for by the Information Quality Act²³) or a science-centered NGO watchdog (e.g. ScienceWatch²⁴) and invoke a broader and more transparent

²² The proposal is outlined in detail at Beth Simone Noveck, “Peer to Patent”: *Community Patent Proposal* (April 2006), available at <http://dotank.nyls.edu/communitypatent/proposals.html>.

²³ Information Quality Act, Pub. L. No. 106-554, § 515(a) (2001).

²⁴ E. Donald Elliott, *Strengthening Science’s Voice at the EPA*, 66 L. & CONTEMP. PROBS. 45, 53 (2003) (“Perhaps it is time for science qua science to get into the game by organizing a

vision of open and collaborative expertise. We have both the tools and the know-how that enable us to organize open networks of expert participation in governmental decision making. Open examination has the advantage of being both more expert and more participatory while avoiding the lack of transparency, that plagues traditional peer review. With open examination, we can, first, improve patent quality by opening up review to the scientific community to remedy the information deficit, and, subsequently, apply the same approach to administrative decision making generally. This proposal has far-reaching implications for the ways we might use scientific expertise in policymaking.

By redesigning the model for patent examination, this proposal points the way forward toward a new approach for administrative law, not by “Daubertizing” judicial review nor by reforming statutory standards²⁵ but by improving agency institutional practice. Introducing technology to bring about open review, instead of peer review, might enhance the institutional competence of the

nongovernmental organization of independent environmental scientists whose only common interest is speaking up for the integrity of science in the process. For purposes of discussion, I will call this imaginary new entity “Science Watch.”).

²⁵ Current reform proposals include altering the definition of patentable subject matter, changing the definition of obviousness, abolishing the concept of constructive reduction to practice, narrowing the scope of willful infringement, changing the standards of judicial review and the presumption of patent validity and curtailing the availability of injunctions. Matthew Sag and Kurt Rohde, *A Differential Impact Analysis of Patent Reform*, Section B2 “Doctrinal Reform,” Aug 12, 2006, (unpublished manuscript available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/sag.doc>) (discussing substantive statutory reform proposals). See also Jay Dratler, *Invention is a Process, or Why the Electronics and Pharmaceutical Industries are at Loggerheads over Patents*, Aug. 12, 2006, unpublished manuscript, available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/Dratler.doc> (calling for abolition of constructive reduction to practice and changing the non-obviousness standard).

Patent Office itself. At this juncture when patent reform is uncertain to move either through Congress²⁶ or the US Supreme Court,²⁷ changing the administrative practices of the agency responsible for implementing patent law may be our best opportunity, not only to bring about reform, but also to do so in ways that are data-driven and empirically measurable.

The United States Patent Office announced in its strategic plan (2007-2012) that it will pilot this proposal (on the basis of an earlier draft of this Article) and institute its use for a controlled set of patents to be examined beginning in 2007.²⁸ Companies, including IBM, Microsoft, Oracle, Intel, Hewlett-Packard, and Red Hat have agreed to submit their patents for examination under this open system.

Like the work of Arti Rai and Stuart Benjamin, this Article contends that drawing the comparison between patent examination and administrative practice, while giving rise to the complexities inherent in comparative work, is normatively desirable. Seeing patent examination as a case study of the way science is used in the administrative context shifts our focus to the institutional

²⁶ Recent proposed but as yet not enacted legislative proposals include: The Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005); The Patents Depend on Quality Act, H.R. 5096, 109th Cong. (2006); The Patent Litigation Pilot, H.R. 5418, 109th Cong. (2006). Patent lawyer, academic and blogger, Prof. Dennis Crouch writes: "Substantive patent reform legislation is dead for the year." Patently-O Weblog, http://www.patentlyo.com/patent/2006/07/patent_reform_i.html (July 28, 2006).

²⁷ *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 2004 U.S. App. LEXIS 11248 (Fed. Cir., 2004), *cert. denied*, 126 S. Ct. 2976 (June 30, 2006) (dismissing writ of certiorari as improvidently granted). While the Supreme Court has heard other patent-related cases this year,, the much-anticipated case reviewing the substantive scope of patentability was not heard.

²⁸ See U.S.P.T.O. Draft Strategic Plan 2007-2012, 71 Fed. Reg. 50048 (2006), available at <http://www.uspto.gov/web/offices/com/strat2007/index.htm> (discussing patent application peer review pilot).

competence of the agency and highlights new opportunities for patent reform.²⁹ Drawing the explicit connections between USPTO and general agency practices³⁰ makes clear that at issue here is not only better quality patents, but more scientifically informed decisions and, thus, a stronger and more legitimate democracy.

There is a substantial administrative policy literature on the role of scientific expertise³¹ and the mechanisms by which agencies procure (or not) information to inform decision making. Because patents used to be confidential

²⁹ Stuart Minor Benjamin and Arti K Rai, *Who's Afraid of the APA? What the Patent System can Learn from Administrative Law*, 95 GEORGETOWN L. J. ____ (2006). Also available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=897307. See also, Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes – Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FL. ST. U. L. REV. 119 (2005) (proposing multi-tiered patent application and examination system); Joseph Farrell and Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERK. TECH. L. J. (2004) (arguing that judicial review cannot fix the patent problem alone and urging better USPTO funding and higher standards of initial review, better incentives (not limited to formal duties) for applicants to find and disclose prior art information, and the creation of a cheap and workable administrative post-issue review.).

³⁰ For another proposal that takes patent law in its administrative context, see Kali N. Murray, *Rules for Radicals*, (August 11, 2006) (unpublished manuscript, presented at IP Scholars Conference, Berkeley, California) (arguing that three key mechanisms – expanded standing, citizen suits, and transparency – which allow environmental law to maintain a robust participation of diverse constituencies, are absent from patent law.), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/Murray.doc>.

³¹ See Special Issue: AM. J. OF PUB. HEALTH, *Scientific Evidence in Public Policymaking* (Vol. 95, S1, July 2005). PHILIP KITCHNER, *SCIENCE, TRUTH AND DEMOCRACY* (2001); BRUCE L.R. SMITH, *THE ADVISERS: SCIENTISTS IN THE POLICY PROCESS 1* (1992); SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICY MAKERS* (1990); Dagmar Lohan, *A Framework For Assessing the Input of Scientific Information Into Global Decisionmaking*, 17 COLO. J. INT'L ENVTL. L. & POL'Y 1, 17625 (2006); Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits Of Science In Setting Risk Standards*, 152 U. PA. L. REV. 1255 (2004); Wendy Wagner, *Science in the Regulatory Process: The "Bad Science" Fiction: Reclaiming The Debate Over The Role Of Science In Public Health And Environmental Regulation* 66 L. & CONTEMP. PROB. 63 (2003); Jerry Mashaw, *Science In The Regulatory Process: Law And Engineering: In Search Of The Law-Science Problem*, 66 L. & CONTEMP. PROB. 135 (2003); Daniel C. Esty, *Toward Optimal Environmental Governance*, 74 N.Y.U.L. Rev. 1495 (1999); Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613(1995). See also BRUNO LATOUR, *THE POLITICS OF NATURE: HOW TO BRING THE SCIENCES INTO DEMOCRACY* (2004); *POLITICIZING SCIENCE: THE ALCHEMY OF POLICYMAKING* (William Hough, ed. 2003).

and not published,³² little of this literature describes the intellectual property system per se. Hence the goal of Part II is to set forth the arguments against the use of external scientific expertise. We want to understand the perceived problems with science as a tool for policymaking that have led to its disuse and the resulting information deficit. Again, by science we are referring to relevant outside expertise and experience not experimental verification per se. The perception of science as problematical has resulted in institutional processes that deprive agencies of information.

In Part III, we demonstrate how the distrust of science is producing an information deficit that hampers patent examination. It argues that the patent crisis – whether the problem of patent quality or simply the lack of efficiency in the process – is directly caused, not by faulty standards but by a lack of information in the examination process.

In Part IV, we discuss why traditional peer review is not a solution to the informational deficit because it lacks transparency, has a closed vision of expertise and places undue burdens on scientists and agency officials alike. As traditionally practiced, it also comes too late in the game to be useful to remedy the information deficit that impedes quality decision making.

Part V of this paper lays out the proposal for open peer review and argues for opening up governmental processes, not to input from authenticated experts, but to the community that collectively is likely to have the knowledge

³² In 1999, the Patent Law was amended to provide for publication of patent applications after eighteen months (with exceptions), Intellectual Property and Communications Omnibus Reform Act 1999, Pub. L. No. 106-113 (1999). The law amended these sections of the patent act concerning confidentiality and publication. 35 USC § 102(e), 35 USC § 199(b), 35 USC § 122, 35 USC § 154 and 35 USC § 374 (2004).

and experience required to inform decision making. This section explains how open review addresses the problems, not only with the use of science in policymaking but with peer review as it has traditionally been practiced. Unlike other theoretical proposals for reform, the United States Patent and Trademark Office will pilot this “Peer to Patent” model in practice in 2007. Open review combines the transparency and self-selection of public participation with the information criticality and expertise of peer review. Metaphorically speaking, it marries the practices of *Wikipedia* to the authority of administrative law.³³

Finally, we conclude with a section on institutional competence, putting forth the claim that by applying technology to improve the patent examination process itself, we are, in fact, able to bring about law reform faster and more effectively than traditional strategies that regard Congress and the courts as the only institutional mechanisms for reform. Where Congress has failed to pass reform legislation and the Supreme Court has declined to review the scope of patentable subject matter, Community Patent Review is being adopted in practice. Patent examination is urgently in need of improvement to remedy the informational deficit that gives rise to low quality patents. At the same time, the empirical lessons to be learned from reforming the institution of the United States Patent and Trademark Office promise to redound to the benefit, not only of intellectual property law and policy, but of administrative rulemaking more

³³ Nicholas Varchaver, *Patent Review Goes Wiki*, FORTUNE MAGAZINE, Aug. 21, 2006, at 18, available at http://money.cnn.com/magazines/fortune/fortune_archive/2006/08/21/8383639/index.htm?source=yahoo_quote.

broadly. Open review offers the structure by which to tie public participation to governmental decision-making in ways that are manageable and useful, allowing us to reintroduce science into lawmaking while, at the same time, preserving its democratic legitimacy.

Part II: The Use of Science in Policymaking: Arguments For and Against

The Energy Research Advisory Board, the group of external scientific advisors that provided impartial expert advice to the Secretary of Energy since 1978, was disbanded this May. The current Administration regularly replaces experts on agency advisory panels with ideologues and political allies. “The Bush administration for years has been stung by criticism that it has censored government scientists, manipulated research results, and conducted political “litmus tests” of prospective scientific advisory board members,” reports *The Scientist Magazine*.³⁴ On February 18, 2004, 62 preeminent scientists including Nobel laureates, National Medal of Science recipients, former senior advisers to administrations of both parties, numerous members of the National Academy of Sciences, and other well-known researchers released a statement titled *Restoring Scientific Integrity in Policy Making*. In this statement, the scientists charged the Bush administration with widespread and unprecedented “manipulation of the

³⁴ Ted Agres, *Panel Faults U.S. Science Policy National Science Board Finds Lack of Consistent Policy for Exchange of Government Research*, *THE SCIENTIST*, June 6, 2006, available at <http://www.the-scientist.com/news/display/23575/>.

process through which science enters into its decisions.”³⁵ This is not an entirely new practice. The EPA Administrator under Reagan fired most of the scientists on its Science Advisory Board and replaced them with Republicans.³⁶ Every year government agencies, especially the EPA, are accused of playing politics³⁷ under the guise of science and depriving themselves of access to outside information.

We are at the nadir of a historical progression since World War II away from trust in scientific expertise in policymaking. Or, more accurately, administrative agencies have brought scientific research in-house, relying on internal expertise and using the scientific profession largely to validate research after-the fact. Because of a prevailing distrust of science and the belief that, to be democratically legitimate, agency decision making must be performed by the agency and not by outsiders, we are evolving increasingly ill-informed government institutions. “Although good science is crucial to sound, efficient, and effective regulations, agency decisions too often either disregard scientific evidence or reflect public policy considerations merely masked as science.”³⁸ This Section unpacks the arguments for and against the use of science in policymaking. While not focused on patents, specifically, it is crucial to the

³⁵ Union of Concerned Scientists Report, *Scientific Integrity in Policymaking: An Investigation into the Bush Administration Misuse of Science*, March 2004, available at http://www.ucsusa.org/assets/documents/scientific_integrity/RSI_final_fullreport_1.pdf

³⁶ E. Donald Elliott, *Strengthening Science’s Voice at the EPA*, 66 LAW & CONTEMP. PROBS. 45, 46 (2003).

³⁷ Union of Concerned Scientists Report, *Surveys of Scientists at Federal Agencies* (showing pervasive pattern of political interference) (last updated, March 2, 2006), available at http://www.ucsusa.org/scientific_integrity/interference/fda-scientist-survey.html.

³⁸ Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, 9 (2003).

theory about information deficit and to the policy proposal to understand the sources of the prevailing distrust of science and reluctance to use outside information.

Proponents marshal numerous arguments in support of the use of scientific expertise in policymaking. First and foremost among these contentions is that science remedies the democratic deficit of agencies by tempering discretion and tethering it to objective fact. The scientific elite, unlike agency officials, is insulated from the political fray and less prone to be unduly influenced. Reducing regulatory discretion is, at least in theory, a prime mover for including scientists in the policymaking processes. Second, science informs policymaking with fact. Fact-based policymaking ensures that we make rational decisions in the public interest to enhance public safety and well-being. We want to know that the rules we make will work. That requires basing them in some sort of predictive scientific fact. Third, with the rise in the amount and scope of regulation over the years,³⁹ it is, arguably, important that those rules be based on empirical reality that comes from the scientific method. While legislation is a question of values, regulation, so the argument goes, must take those value-based decisions made by Congress and apply them to concrete facts.

³⁹ CLYDE WAYNE CREWS, JR., *TEN THOUSAND COMMANDMENTS: AN ANNUAL SNAPSHOT OF THE FEDERAL REGULATORY STATE* 9 fig.6 (2003) (illustrating the number of Federal Register pages from 1993 to 2002). According to figures compiled from the National Archives and Records Administration, 4187 rules were proposed in 2002. See also CORNEULIS KERWIN, *RULEMAKING: HOW GOVERNMENT AGENCIES MAKE LAW AND WRITE POLICY* (1994). Kerwin cites the following: in 1981 there were 6,481 rules published, in 1991, there were 4,413 rules published, in 2001 there were 19,643 rules published. To understand the growth of rulemaking practice, however, it is illustrative to look at the number of pages of regulations in the Code of Federal Regulations. In 1938, the page count was, for example, 1, 174 for agriculture, 39 for labor and no environmental regulations (there was no EPA). By 2001, that number was 10,406 for agriculture, 5,385 for labor and 19,385 pages of environmental rulemaking activity.

The decision about the number of parts per billion of asbestos or lead in the air and water should not be made democratically but based on scientific know-how as to what is safe. Science helps to translate the democratic mandate from the statute to create a clean environment into a set of considered practical standards and practices. Since the role of agencies is to collect the data necessary to set those standards, rather than to pronounce general laws, science has an important role to play here.⁴⁰

Paying lip service to the importance of good science and quality information, says little about the institutional mechanisms or structures by which science is integrated into governance. There is a fourth rationale that proposes greater accountability to and decision making by the scientists because of their unique mindset. Pro-science advocates suggest that scientific professionals should play a greater role in decision making processes. Because of their adherence to the scientific method and its rigors, scientists stand in a special position, not only to withstand political influence, but to weigh complex questions of policymaking with impartiality. "I offer a conception of the scientist as artisan," writes historian of science Arnold Pacey, "as a worker capable of offering to the broader community something of genuine value, whose contributions can be, and should be, responsive to a much wider range of concerns than are usually taken to be appropriate."⁴¹ In Francis Bacon's *New Atlantis*, Bacon describes the island of Bensalem. "Here mariners are treated with great hospitality, and they are surprised by the wisdom and generosity, and

⁴⁰ SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS* 4 (1990).

⁴¹ ARNOLD PACEY, *TECHNOLOGY IN WORLD CIVILIZATION*, 4 (1991).

incorruptibility of the island's government." The leadership is founded upon the institution of an "elite group of investigators."⁴² Whether intended as a parody or not, Bacon expresses the belief that as a profession, science because of the rigors of its method, is a foundation for good government. This deference to expertise stands in contrast to the narrower view of Sheila Jasanoff. She (and others) take the view that scientific expertise is particularly valuable, not in all circumstances, but when there is a problem to be solved with a well-defined scope, there is complex data required but not formulations of basic policy.⁴³ These conceptions, despite their contrasts, view the scientific expert as standing in a special position to inform the processes of governance and provide the political official with policymaking options.⁴⁴ Even where people disagree about the model of governance and whether competence ought to reside with federal, state or local officials, good scientific information can produce better decisions at every level.

For every argument in favor, there are, however, at least two against. The role of science in policymaking is waning. This is not to suggest that agencies do not use science, merely that it is considered a necessary but not sufficient ingredient of regulation. This, in turn, is leading to a reluctance to

⁴² PHILIP KITCHNER, *SCIENCE, TRUTH AND DEMOCRACY*, 7 (2001).

⁴³ SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS*, 10-11 (1990).

⁴⁴ Roger Pielke, Jr., *When Scientists Politicize Science*, *REGULATION*, Spring 2006, at 28 (A better alternative is for the scientific community to take some responsibility to address the policy significance of scientific results. This would mean not simply seeking to better "communicate" the results of science to the policymaker, but developing the capability to place science into policy context, i.e., to address the question of what policy alternatives are consistent with and inconsistent with scientific results. If the scientific community wishes to claim independence from partisan politics, then with this comes an obligation to provide independent guidance on the significance of science for a wide scope of policy alternatives. Instead of the futile effort to keep science and politics separate, it may make more sense to ask scientists to engage more substantively in policy debate, not by taking sides but instead by serving as "honest brokers of policy options.").

consult outside experts and an information deficit. Legislative considerations, not science, are meant to determine the regulatory agenda. Former EPA General Counsel E. Donald Elliott has documented the "decline of science as an important determinant in environmental decision making."⁴⁵ We are replacing scientific experts with political appointees.⁴⁶ Even with the additional Federal Advisory Committees⁴⁷ and Science Boards⁴⁸ and peer review mandates,⁴⁹ the emerging trend over the last fifty years is away from reliance on extra-agency input. This is perhaps the reason it was necessary to enact an executive order to mandate its

⁴⁵ E. Donald Elliott et al., *Science, Agencies, and the Courts: Is Three a Crowd?*, 31 ENVTL. L. REP. 10,125, 10,126 (2001).

⁴⁶ Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, 11 (2003) ("Through detailed reports and analyses, the General Accounting Office ("GAO") has consistently documented EPA's faulty scientific methods as well as its practice of obscuring the policy-based reasons for some of its decisions. GAO recently noted concern among observers 'about whether [EPA and other] agencies' procedures and assumptions are sufficiently transparent, thereby providing decision-makers and the public with adequate information about the scientific and policy bases for agencies' risk estimates as well as the limitations and uncertainties associated with those estimates.' GAO has also cited gaps and inaccuracies in EPA data that further compromise the agency's ability to assess risks and set risk-based priorities. These gaps, in part, explain EPA's heavy reliance on assumptions.")

⁴⁷ Federal Advisory Committee Act (FACA), Pub. L. 92-463, 5 U.S.C., App 2 6(c) (1972). There are over 800 Federal Advisory Committees today. The Federal Advisory Committee Database is available at <http://fido.gov/facadatabase/>. See also, The Twenty-Seventh Annual Report to the President on Federal Advisory Committees, U.S. General Services Administration, available at <http://fido.gov/facadatabase/printedannualreports%5C1998-TwentySeventh%20Annual%20Report%20Of%20The%20President%20On%20Federal%20Advisory%20Committees.pdf>. Additional documents on peer review available on the Office of Management and Budget website on Information Policy, E-Gov and IT, at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>.

⁴⁸ U.S. GEN. ACCOUNTING OFFICE, EPA'S SCIENCE ADVISORY BOARD PANELS: IMPROVED POLICIES AND PROCEDURES NEEDED TO ENSURE INDEPENDENCE AND BALANCE, GAO-01-536 (2001); Robert F. Blomquist, *Integrated Pollution Control: A Symposium: & Article: The Epa Science Advisory Board's Report On "Reducing Risk": Some Overarching Observations Regarding The Public Interest*, 22 ENVTL. L. REP. 149 (1992).

⁴⁹ See Off. of Mgmt. and Budget, JOSHUA B. BOLTEN, ISSUANCE OF OMB'S FINAL INFORMATION QUALITY BULLETIN FOR PEER REVIEW, OMB Memorandum M-05-03 (Dec. 16, 2004).

consideration. Executive Order 12,866 enacted in 1993 declared that “each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.”⁵⁰

What are the arguments, therefore, against relying on too much scientific expertise or creating mechanisms for greater accountability to the scientific profession? How did we get to this point of entrenched distrust of scientific expertise?

While proponents laud the use of expertise as a remedy to democratic deficiencies, critics point out that scientific expertise is both undemocratic and unaccountable. Science, like managerial expertise, cannot and should not substitute for democratic decision-making. It can inform policymaking with fact but the “reality is,” writes environmental activist and administrative law scholar David Schoenbrod, “that science is surprisingly uncertain.”⁵¹ Rarely does consensus exist around regulatory issues such as environmental hazards.

⁵⁰ Regulatory Planning and Review, Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

⁵¹ As Harvard administrative law scholar, Gerald Frug notes, this was the era of the “expertise model” of governance that legitimated bureaucracy in a democracy by reference to its positivist groundings. Gerald Frug, *The Ideology of Bureaucracy in American Law*, 97 HARV. L. REV. 1276, 1283-84 (1984) (“Progressives and certain New Dealers--including organization theorists like Philip Selznick, corporate managerialists like Chester Barnard, Elton Mayo, Peter Drucker, and Douglas McGregor, and administrative law scholars like Woodrow Wilson and James Landis -- agreed with the charge that bureaucracies were not in fact controlled by commands issued from outside. They recognized the enormous range of discretion exercised by bureaucratic managers; indeed, they argued that this discretion was not only an unavoidable ingredient of bureaucratic life but also its very *raison d'etre*. Instead of fearing bureaucratic discretion, these thinkers welcomed it because they perceived the managers and employees who exercised it to be 'experts' whose professionalism simultaneously limited the scope of their power, prevented personal domination, and made possible the creativity and flexibility necessary to the effectiveness of the bureaucratic form.”)

Instead, regulators and politicians invoke science as a justification for politics. Bureaucrats use science to avoid accountability for politics; scientists, it is complained, are often lobbyists in disguise. "Studies of scientific advising leave in tatters the notion that it is possible, in practice, to restrict the advisory process to technical issues or that the subjective values of scientists are irrelevant to decision making."⁵² Agencies practice politics and manipulate science to suit ideological ends. Wendy Wagner famously writes of the "science charade"⁵³ and Schoenbrod talks of "co-opting the legitimacy of science."⁵⁴ He goes on to give numerous examples to illustrate what he views as the fallacy of scientific impartiality; or, more accurately, the way agency politics are invoked to manipulate and distort legitimate scientific research, leading to decisions based on bad information. "[T]he EPA hired the National Academy of Sciences (NAS) to study whether lead pollution is harmful. The NAS is the citadel of science in Washington, but science in Washington is sometimes politics by other means. The NAS appointed a panel slanted in favor of the lead-additive makers and their allies in the petroleum and lead industries. According to *Science* magazine, the panel included four industry employees, but 'no identifiable 'environmentalist'...as a counterpoise to industry's weight.'⁵⁵ Schoenbrod, like others, points out that we have not been able to come to terms about appropriate

⁵² SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICY MAKERS*, 230 (1990).

⁵³ Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 34453 (1995); Wendy Wagner, *Science In The Regulatory Process: The "Bad Science" Fiction: Reclaiming The Debate Over The Role Of Science In Public Health And Environmental Regulation*, 66 L. & CONTEMP. PROB. 63 (2003);

⁵⁴ DAVID SCHOENBROD, *SAVING OUR ENVIRONMENT FROM WASHINGTON* 221 (2005).

⁵⁵ DAVID SCHOENBROD, *SAVING OUR ENVIRONMENT FROM WASHINGTON* 30 (2005).

levels of lead for children, for example. We cannot reliably conclude that certain toxins released into our water are, in fact, dangerous.

Where there is no scientific consensus, we cannot legitimately base decisions on science and must avoid biased and prejudicial information. But it is not just a question of scientific certainty.⁵⁶ Even if science were to be a reliable determinant, there is another critique – a variation on the theme about democratic legitimacy – that argues against making decisions on the basis of science rather than on the basis of values. Even where we can identify health and safety risks with some precision, the democratic mandate demands that decision-making in the public interest must be driven by other factors as well. We have to consider “facts on the ground”⁵⁷ and how they are impacted, what their concerns are and what solutions they might propose. Schoenbrod tells the story of the small-scale cider farmers in upstate New York and New England and how they devised a better and less expensive plan to protect the public than the stringent rules on pasteurization called for by the FDA. Science, which might dictate safe levels of bacteria, does not solve the problem of how to get to those safe levels. Only localized decision making with the benefit of that knowledge and experience, suggests Schoenbrod, can solve the problem.

⁵⁶ Matthew Sag and Kurt Rodhe, A Differential Impact Analysis of Patent Reform 6 (draft dated Aug 12, 2006), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/sag.doc> (quoting STEPHEN TOULMIN, RETURN TO REASON 204-214 (2001)). “[A] demand for ‘conclusive proof’ of a proposition may itself simply reflect a preoccupation with a narrow mathematical form of reasoning modeled on the scientific method, and a futile quest for certainty where certainty is not possible.”).

⁵⁷ DAVID SCHOENBROD, SAVING OUR ENVIRONMENT FROM WASHINGTON 13 (2005).

It would be simplistic to suggest that agencies are not relying on science. They cannot do their work without it. But the belief and trust in science, the willingness to permit scientific input and review before a decision is made, are on the decline. Over time, we have shifted toward a vision of agencies as managing social interests and weighing values rather than one of agencies managing expertise⁵⁸ This acknowledges the political pressures of governance even within the agency. While agencies have always had to balance interests and rely on expert, scientific information, the prevailing legal realist view is that agencies are subject to political pressure and should avoid the use of outside expertise.

While in 1972, there were 1400 Federal Advisory Committees by 1982, there were 878. By 1992 the number increased to 1141 but only 33% of those were established on the basis of agency authority (as opposed to legislative mandate) and in 1998 the number once again dropped to 892 with 28% chartered under agency authority.⁵⁹ Of course, these numbers alone do not convey the entire picture of who served on these committees, whether they were from academic or industry science and what account, if any, was taken of their work. Federal Advisory Committees are, in any case, coming under fire for beign

⁵⁸ See Ernest Gellhorn, *Public Participation in Administrative Proceedings*, 81 YALE L.J. 359, 360 (1972) ("The 'public interest' . . . is not a monolith," writes Gellhorn. "It involves a balance of many interests and the presentation of otherwise unrepresented views should be viewed as a potential aid rather than a hindrance to agency operations.").

⁵⁹ FACA Database available at http://www.gsa.gov/Portal/gsa/ep/contentView.do?programId=9137&channelId=-13170&oid=9673&contentId=14451&pageTypeId=8203&contentType=GSA_BASIC&programPage=%2Fep%2Fprogram%2FgsaBasic.jsp&P=MC.

essentially ideological rather than scientific mouthpieces.⁶⁰ But the declining numbers and the Executive Order⁶¹ in 1993 to cut Federal Advisory Committees for being wasteful and ineffectual, give some indication. Agencies are taking scientific research in-house and, whether for improper reasons of political ideology or for appropriate reasons of avoiding political manipulation, they take less account of science and have become less transparent about the information used in their decision making.

This shift away from science is accelerated by the fact that courts are not required and, in fact, will not review agency decisions based on a supposed lack of adequate scientific information.⁶² As the Supreme Court held in *Vermont Yankee*, an agency may only be reviewed for failing to follow a statutory mandate not based on the quality of the information as such.⁶³ While there have been cases criticizing an agency's use of science,⁶⁴ on the whole, courts defer to agency determinations about science.⁶⁵ "[M]any panels defer excessively to any agency

⁶⁰ See *Defending Science, Federal Advisory Committees* at http://www.defendingscience.org/public_health_regulations/Federal-Advisory-Committees.cfm (last visited Aug. 29, 2006).

⁶¹ *Termination and Limitation of Federal Advisory Committees*, Exec. Order 12838, 58 Fed. Reg. 8207 (Feb 10, 1993), available at <http://www.presidency.ucsb.edu/ws/index.php?pid=61534>.

⁶² see Stephen Merrill, *Forward*, 66 L. & Contemp Problems 2 (2003).

⁶³ *Vermont Yankee Nuclear Power Corporation v. Natural Resources Defense Council*, 435 U.S. 519; 98 S.Ct. 1197; 55 L. Ed. 2d 460 (1978).

⁶⁴ Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, 19 (2003).

⁶⁵ See, e.g. *Sigma-Tau Pharma v. Schwetz*, 288 F.3d 141, 146 (4th Cir. 2002) (the "broad deference" due the agency "is all the more warranted when, as here, the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'") *Thomas Jefferson Univ.*, 512 U.S. at 512 (quoting *Pauley v. Beth Energy Mines, Inc.*, 501 U.S. 680, 697, 115 L. Ed. 2d

action that contains a scientific component. In some instances courts effectively avoid judicial review entirely, preferring instead to defer blindly to an agency's decision regardless of its sometimes even obvious flaws. Such judicial passivity does not enhance democratic accountability. *Chevron*⁶⁶ and *Daubert*⁶⁷ teach that courts need not -- and must not -- venture into the merits of competing or complex scientific findings."⁶⁸ Judicial deference to decisions based on science only produce a greater incentive for agencies to legitimize their decisions on the basis of what is often junk science⁶⁹ but gives the appearance of credibility.

While science is losing the battle, because the result is declining quality of decision making, it is the public that ultimately loses the war.

Information Deficit and Patent Quality

604, 111 S. Ct. 2524 (1991)); see also *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 865 (1984) (sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency. ... "in these cases the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: the regulatory scheme is technical and complex, the agency considered the matter in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies. Congress intended to accommodate both interests, but did not do so itself on the level of specificity presented by these cases. Perhaps that body consciously desired the Administrator to strike the balance at this level, thinking that those with great expertise and charged with responsibility for administering the provision would be in a better position to do so; perhaps it simply did not consider the question at this level; and perhaps Congress was unable to forge a coalition on either side of the question, and those on each side decided to take their chances with the scheme devised by the agency. For judicial purposes, it matters not which of these things occurred.)

⁶⁶ *Chevron U. S. A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

⁶⁷ *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

⁶⁸ Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, 28 (2003).

⁶⁹ PETER W. HUBER, *GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM* 1-6 (1991).

There was enough of a sense that agencies are making decisions without the benefit of the best or the right scientific information that Congress felt compelled to pass the Information Quality Act in 2001 (IQA).⁷⁰ Its goal (in theory if not in practice) is to improve government policymaking by changing the information upon which the government can rely to make decisions. It is intended to improve quality and, at the same time, increase public participation and improve information disclosure by agencies. Regardless of whether the law has any salutary effect (and administrative law scholar Steven Johnson vehemently argues that it does not), there is a prevailing information deficit resulting from the war on science. Nowhere is that more the case and nowhere are the effects more obvious than in the case of patents and patent examination practice.

A consensus is emerging that there is a crisis of “patent quality.” Because of a lack of access to adequate information and to the knowledge of how to apply it most effectively, the USPTO is granting undeserving applications. Bureaucrats are supposed to possess “the knowledge that comes from specialized experience.”⁷¹ Yet the reality is that the supposedly expert bureaucrat – in this case fifty-five percent of patent examiners – has been at the USPTO for fewer

⁷⁰ Information Quality Act, 35 USC § 3516; Pub. L. No. 106-554, para 515, 114 Stat. 2763A-153-154 (Dec. 21, 2000). Implemented by the Office of Mgmt. & Budget, Information Quality Guidelines, 67 Fed. Reg. 369 (Jan. 3, 2002), reissued with corrections, 67 Fed. Reg. 8452 (Feb. 22, 2002).

⁷¹ Richard B. Stewart, *The Reformation of American Administrative Law*, 88 Harv. L. Rev. 1669. 1678 (1975).

than two years.⁷² It is not surprising given the fact that they are getting paid approximately \$55,000 and a first-year associate in a Manhattan law firm earns a base salary of \$125,000. In addition to being underpaid, they are also overworked.⁷³ An examiner has an average of 18-20 hours to do the initial review of an application.⁷⁴ Arguably, we have returned to the registration regime we abandoned in 1836.⁷⁵

Patent bureaucrats enjoy a great deal more discretion than their counterparts at other agencies. They have responsibility for granting a twenty-year monopoly with limited supervision, oversight or review when a first or second year civil servant at another agency would be drafting memos. The wide-ranging discretion of agency officials would not be such a problem, Adam Jaffe and Josh Lerner point out in *Innovation and Its Discontents*, were it not for the fact that courts are increasingly likely to find in favor of patent holders.⁷⁶ The

⁷² ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* 136 (2004).

⁷³ Gregory Aharonian, *A Few Patent Examiners Complain About Patent Quality*, PATNEWS, (January 28, 1999).

⁷⁴ H.R. REP NO. GAO-05-720 (June 15, 2005). *The USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain* (depending on the type of patent and the skill level of the examiner, each examiner is expected to process an average of 87 applications per year at a rate of 19 hours per application. United States Government Accountability Office Intellectual Property The USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain). See also, Brenda Sandburg, *Speed Over Substance?*, INTELL. PROP. MAGAZINE (March 1999).

⁷⁵ J. Giles and S. Rich, *Laying the Ghost of the "Invention" Requirement* 14 FED. CIR. B.J.163, 165 (2005) (We had an examination regime from 1790 to 1793 and then adopted a registration system from 1793 to 1836 but the outcry was so great that we had to return to examination and created the modern Patent Office to handle the work.).

⁷⁶ James Bessen & Michael J. Meurer, *Lessons For Patent Policy From Empirical Research On Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 22 (2005) ("There is also direct evidence that the Federal Circuit has changed patent validity and patent scope. The research must be used cautiously though, because it does not control for the selection effect. Allison and

Supreme Court rarely hears patent-related certiorari petitions⁷⁷ (2006 being a notable exception).⁷⁸

Patents are consequently both stronger, easier to get and more likely to be upheld without any concomitant guarantee of their quality. This has led to a system that sometimes rewards invention at the expense of innovation. In other words, the inventor may receive the boon of the patent monopoly but the “useful arts,” that the Constitution aims to advance are not promoted. Instead, the current system has generated tremendous uncertainty with regard to the role patents play in the marketplace. Whether the cause or the effect, there are

Lemley find the patent validity rate has increased since the creation of the Federal Circuit. Lunney finds that the Federal Circuit is less likely to find infringement than predecessor courts and thus has narrowed patent scope. Wagner and Petherbridge find Federal Circuit claim interpretation decisions are growing more predictable.”); see also Jay P. Kesan and Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, U Ill. L. & Econ. Research Paper (2005) (“[S]ignificant percentage of cases (about 8-9%) are resolved on the merits through summary judgment. Consequently, summary judgments are important in patent cases for determining patent validity and infringement, and the summary judgments related to patent validity occur earlier in the litigation compared to summary judgments related to patent infringement. This result is somewhat encouraging given the important role played by the courts in revoking patent rights improvidently granted at the outset by the PTO. Nevertheless, despite the fact that such rulings occur early in the proceedings compared to patent trials, we should still be concerned about the huge transaction costs associated with patent litigation because summary judgments in general, and summary judgment based on invalidity in particular, are expensive compared to summary judgments granted on other grounds.”), available at <http://ssrn.com/abstract=808347>.

⁷⁷ Mark D. Janis, *Intellectual Property Challenges in the Next Century: Patent Law in the Age of the Invisible Supreme Court*, 2001 U. Ill. L. Rev. 387, 387 (2001) (The Supreme Court has rendered itself well nigh invisible in modern substantive patent law. The Court of Appeals for the Federal Circuit, created in 1982, has become the de facto supreme court of patents.).

⁷⁸ See generally *eBay Inc. v. MercExchange, LLC.*, 126 S. Ct. 1565 (2006); *Illinois Tool Works, Inc., v. Indep. Ink, Inc.*, 126 S. Ct. 1281 (2006); *LabCorp v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 165 L. Ed. 2d 399 (2006)(dismissing writ of cert.); *MedImmune, Inc. v. Genentech, Inc.*, 126 S. Ct. 1329 (2006); *KSR Intn’l v. Teleflex*, 126 S. Ct. 2965 (2006).

double the number of patent applications today and the backlog has risen to over 1 million.

In practice, the examiner has too little information or too little knowledge of how to apply available information in order to render a decision. The examiner searches an internal Patent Office database containing U.S. and foreign patent applications and certain journals in an effort to find prior art. While some examiners might use Google to look up information online, the use of Internet research is severely restricted for security reasons. In more than half the technology centers⁷⁹ (formerly known as examining groups) at the USPTO, Internet research is forbidden.⁸⁰ He is limited to those sources he can find on his own from the office.

This gives rise to a “goldilocks” problem: too little information, too much information and none of it just right.⁸¹ In searching for prior art, know-how that

⁷⁹ For a list of the USPTO Technology Centers, see <http://www.uspto.gov/web/info/pat-tech.htm>.

⁸⁰ U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, MANUAL OF PATENT EXAMINING PROCEDURES (MPEP) 904.02(c) (8th ed. 2004) (“When the Internet is used to search, browse, or retrieve information relating to a patent application which has not been published, other than a reissue application or reexamination proceeding, Patent Organization users MUST restrict search queries to the general state of the art unless the Office has established a secure link over the Internet with a specific vendor to maintain the confidentiality of the unpublished patent application. Non-secure Internet search, browse, or retrieval activities that could disclose proprietary information directed to a specific application which has not been published, other than a reissue application or reexamination proceeding, are NOT permitted. This policy also applies to use of the Internet as a communications medium for connecting to commercial database providers.”). See also Internet Usage Policy, 64 F.R. 33056, Art. 4 (June 21, 1999) (“If security and confidentiality cannot be attained for a specific use, transaction, or activity, then that specific use, transaction, or activity shall NOT be undertaken/conducted.”)

⁸¹ See also, Jay Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERK. TECH. L.J. 763, 763 and 767 (2002) (“It is widely recognized that the Patent Office grants overly-broad patents because it has deficient knowledge of the relevant prior art, especially in high technology areas with significant nonpatent prior art.”).

predates the invention that might pre-empt it and invalidate the patent's claims, such as patents or journal articles, websites or other disclosures that might suggest that the invention is not new, the examiner sometimes turns up nothing. While the patent may sound like something familiar that's come before, often she cannot find other written material that actually teaches the claims of the patent. Alternatively, she is so inundated with related prior art but has trouble in the time allotted to review an application, winnow the material and find art that is relevant and useful for the examination process.⁸² Even if she can find art that is pertinent, she still may have trouble knowing from the perspective of one practicing in that area if the patent is an obvious or non-obvious inventive leap over the combined prior art references.

A patent examiner, especially those who may not use the Internet, must find their information from two computers systems in place at the United States Patent Office: 'EAST' (Examiner's Automated Search Tool) and 'WEST' (Web-Based Examiner Search Tool). In addition, there is a database of foreign patent filing. These databases provide access to prior U.S. patents, foreign patent abstracts, certain pending U.S. applications, and additional proprietary database libraries. Examiners can conduct full-text searching of published applications since 2001 and patents granted since 1970 as well as access optically-scanned copies of patents since 1920.⁸³ Patent applications, of course, also contain

⁸² Eli Kintisch, *US Patent Policy: USPTO Wants to Tap Experts to Help Examiners*, SCIENCE, 19 May 2006 at 982, available at <http://www.sciencemag.org/cgi/content/full/312/5776/982b>.

⁸³ U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, MANUAL OF PATENT EXAMINING PROCEDURES (MPEP) 902.03(e) (8th ed. 2004) ("The automated search tools on examiners' desktop computers include the Examiner's Automated Search Tool (EAST),

references to prior art. Contrary to popular assumption, they do not contain access to the corpus of scientific knowledge.⁸⁴

In Sampat's recent study⁸⁵ of 502,687 utility patents, he finds that examiners have a comparative disadvantage in searching for non-patent prior art or foreign patents.⁸⁶ Interestingly, while patent examiners account for 41% of the citations to previous U.S. patents, they account for only 10% of references to non-patent prior art. "If an applicant does not search for prior art and thereby does not report a piece of relevant prior art on his/her information disclosure statement, the examiner is less likely to discover it if it is codified in the non-patent literature or a foreign patent than if it is codified in a U.S. patent, since examiner capabilities for searching for U.S. patents exceed their capabilities for searching other sources of prior art."⁸⁷

Particularly in cutting-edge areas of innovation where information may not be available in patent applications, examiners are not digging up what they need. Applicants are not required to provide it.⁸⁸ "Because the applicant need

the Web-Based Examiner Search Tool (WEST), and the Foreign Patent Access System (FPAS).").

⁸⁴ Paul Edward Geller, *An International Patent Utopia?*, 25 EUR. INTELL. PROP. REV. 515, 516 (2003) (calling for the creation of open, global databases and the linking of local patent databases into a globally distributed database to facilitate global searching).

⁸⁵ Bhaven Sampat, *Determinants of Patent Quality: An Empirical Analysis* (2006), available at http://siepr.stanford.edu/programs/SST_Seminars/patentquality_new.pdf_1.pdf.

⁸⁶ Bhaven Sampat, *Determinants of Patent Quality: An Empirical Analysis* 3 (2006), available at http://siepr.stanford.edu/programs/SST_Seminars/patentquality_new.pdf_1.pdf.

⁸⁷ Bhaven Sampat, *Determinants of Patent Quality: An Empirical Analysis* 13 (2006), available at http://siepr.stanford.edu/programs/SST_Seminars/patentquality_new.pdf_1.pdf.

⁸⁸ The applicant is required to disclose any information which is material to the prosecution of the patent. Oath or Declaration, 37 CFR 1.63(b)(3) (2004). According to Chisum, "Traditionally, standard practice in the Patent and Trademark Office did not

only provide material information of which he or she is aware, and is not required to search for any of this information, the informational burdens on the examiner are clearly heavy—even before the examiner engages in the heavy lifting of interpreting the prior art.”⁸⁹ Third-party comment, while provided for in the statute,⁹⁰ must be made within a two-month window for a fee and without commentary and is, therefore, rarely invoked.

Under current law, patent examiners may consult databases but they may not consult the public when searching for prior art.⁹¹ The examiner is expected to be scientifically adept enough to discover the prior art on her own. However,

require the applicant to disclose or cite items in the prior art believed to be relevant to the patentability of claims in the application. The examiner searched the prior art and cited relevant items in reasons given for rejection of claims. Furthermore, an applicant and his or her patent attorney were under no duty to conduct a search of the prior art.” Chisum on Patents, 6-19 Chisum on Patents § 19.03 (b) (2006). Sometimes applicants file no prior art at all. See, e.g. Tim Palmer, *Applicants not Citing Any Prior Art: Scary*, Patent Chronicles (March 23, 2005, 3:30 pm), available at <http://www.patentchronicles.com/archives/20050323/applicants-not-citing-any-artscary/> (The USPTO has proposed a rule change to “encourage patent applicants to provide the USPTO the most relevant information related to their inventions in the early stages of the review process. As a result, patent applications could be processed in a more streamlined and effective manner.”). Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (10 July 2006).

⁸⁹ Lee Petherbridge, *Positive Examination*, 46 IDEA 173, 183 (2006).

⁹⁰ Patent Act, 35 U.S.C. § 122(c) (2004). That has been interpreted to mean that only prior art without commentary can be submitted. Hence the Manual of Patent Examining Procedure Rule 1134.01 implementing the Code of Federal Regulations, 37 CFR 1.99, provides that third parties may submit prior art without commentary in response to a published but not-yet-granted application. Within two months of publication, someone may submit no more than 10 patents and publications. They may not highlight or mark up the materials submitted. They must pay \$180 for the privilege of submitting prior art. The patent examiner may not respond to the third party (except to process the fee).

⁹¹ U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, MANUAL OF PATENT EXAMINING PROCEDURES (MPEP) § 1.291(d) (8th ed. 2004) Protests by the Public against Pending Applications. A member of the public filing a protest in an application under this section will not receive any communication from the Office relating to the protest, other than the return of a self-addressed postcard which the member of the public may include with the protest in order to receive an acknowledgement by the Office that the protest has been received.

third parties may, to a limited extent, submit prior art after the publication and before the issuance of a patent. While patent examination is confidential, non-provisional utility applications are published eighteen months after the filing date.⁹²

While the patent examination process is unique, it mimics in many important respects the way agencies make decisions, including ones such as these that have a longstanding impact on the economy and on scientific innovation. The examiner is forced to enact a 20-year grant of monopoly rights on the basis of an internal database and without the benefit of outside information. Whether it's horror stories about the EPA and the Clean Air Act or the Patent Office and the Peanut Butter and Jelly Sandwich Patent,⁹³ the pervasive information deficit problem that has resulted from an absence of adequate scientific expertise in policymaking is causing problems.

Part III: Why Traditional Peer Review is Not the Solution

The traditional solution proposed to remedy the information deficit and information quality problem in administrative agencies is peer review. Peer review provides a mechanism for oversight and quality control of agency science and is a practice in widespread use in government, academia and industry. "Refereeing procedures," such as peer review, writes Sheila Jasanoff, "have come

⁹² MANUAL OF PATENT EXAMINING PROCEDURES (8th ed. 2005), 1120, 37 C.F.R. § 1.211 (2006). In 2005, 291,221 applications were published. USPTO PERFORMANCE AND ACCOUNTABILITY REPORT FOR FISCAL YEAR 2005, *available at* <http://www.uspto.gov/web/offices/com/annual/2005/2005annualreport.pdf>.

⁹³ ADAM B. JAFFE AND JOSH LERNER, INNOVATION AND ITS DISCONTENTS 25ff. (2005).

to be regarded as the most effective method of validating science in two quite different spheres of professional activity: prepublication review of journal articles and screening of applications by federal research sponsoring agencies. There is thus an appealing logic to the syllogism that links peer review to “good science” in the regulatory process.”⁹⁴ As we shall discuss, however, the logic is fallacious. Traditional peer review suffers from considerable problems that make it ill-suited to remedying the information deficit.

Through peer review, researchers allow other experts to examine, criticize and improve their work.⁹⁵ This enhances the quality of science and innovation while maximizing the efficient use of the scarce resource of time. Peer review allows colleagues to evaluate each other and in so doing to “certify the correctness of procedures, establish the plausibility of results, and allocate resources.”⁹⁶

⁹⁴ SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICY MAKERS*, 61 (1990).

⁹⁵ See Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making*, Carnegie Commission, New York 75 (1993). See, e.g. DeploymentLink, *Peer Review Essential for Scientific Advances* (Sept. 1, 2001), available at http://deploymentlink.osd.mil/news/sep01/news_90401_001.shtml (“Scientists say peer review is a critical quality control principle in the planning, design, conduct and interpretation of scientific research. Peer review of research reflects scientists’ commitment to careful and objective pursuit of knowledge. Through peer review, researchers allow other experts to examine, criticize and improve their work.”)

⁹⁶ DARRYL J. CHUBIN, EDWARD J. HACKETT, *PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY* 2 (1990).

Peer review⁹⁷ is in common use in government.⁹⁸ The National Science Foundation and the National Institutes of Health both use peer reviewers to determine if research is novel and represents a contribution to its field.⁹⁹ The National Science Foundation currently relies on a network of over 50,000 reviewers.¹⁰⁰ The National Institutes of Health relies on outside review groups and advisory councils from the scientific community to review over 70% of its applications.¹⁰¹ The Environmental Protection Agency grant selection process

⁹⁷ U.S. GEN. ACCOUNTING OFFICE, DEPARTMENT OF EDUCATION: COMPLIANCE WITH THE FEDERAL ADVISORY COMMITTEE ACT AND LOBBYING RESTRICTIONS, GAO/GGD/OGC-00-18 (Dec. 30 1999); U.S. GEN. ACCOUNTING OFFICE PEER REVIEW: COMPLIANCE WITH THE PRIVACY ACT AND FEDERAL ADVISORY COMMITTEE ACT, GAO/GGD-91-48 (Apr. 17 1991); U.S. GEN. ACCOUNTING OFFICE, PEER REVIEW: EPA NEEDS IMPLEMENTATION PROCEDURES AND ADDITIONAL CONTROLS, GAO/IRCED-94-98 (Feb. 22 1994); U.S. GEN. ACCOUNTING OFFICE, FEDERAL ADVISORY COMMITTEES: ADDITIONAL GUIDANCE COULD HELP AGENCIES BETTER ENSURE INDEPENDENCE AND BALANCE, GAO-04-328, (Apr. 1 2004); U.S. GEN. ACCOUNTING OFFICE, FEDERAL RESEARCH: PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY, GAO/RCED-99-99 (Mar. 1 1999); U.S. GEN. ACCOUNTING OFFICE, PEER REVIEW: REFORM NEEDED TO ENSURE FAIRNESS IN FEDERAL AGENCY GRANT SELECTION, GAO/PEMD-94-1 (Jun. 24 1994); U.S. GEN. ACCOUNTING OFFICE, FEDERAL ADVISORY COMMITTEES: GSA'S MANAGEMENT OVERSIGHT AND GAO COMMENTS LEGISLATIVE AMENDMENTS, GAO/T-GGD-890 1 (Oct. 5 1998); U.S. GEN. ACCOUNTING OFFICE, UNIVERSITY FUNDING: INFORMATION ON THE ROLE OF PEER REVIEW AT NSF AND NIH, GAO/WED-87-87FS (Mar. 26, 1987); U.S. GEN. ACCOUNTING OFFICE, FEDERAL ADVISORY COMMITTEE ACT: GENERAL SERVICES ADMINISTRATION'S MANAGEMENT ADVISORY ACTIVITIES, GAO/GGB89-10 (Oct. 5 1988).

⁹⁸ See Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1045 (2000). See also, Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 24 ENVTL. L. REP. 10064 (2004).

⁹⁹ Cf. J.B. Ruhl, *Prescribing The Right Dose Of Peer Review For the Endangered Species Act*, 83 NEB. L. REV. (2004) (discussing scientific peer review and arguing against excessive reliance on peer review).

¹⁰⁰ National Science Foundation, *How We Work* (Jul 15, 2005) at <http://www.nsf.gov/about/how.jsp> (last visited Sept. 30, 2005). See also Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 BERK. TECH. L.J. 1, 7 (1994).

¹⁰¹ See National Institutes of Health, Center for Scientific Review, at <http://cms.csr.nih.gov/AboutCSR/Welcome+to+CSR> (last updated Aug. 4, 2005).

relies heavily upon “Science Review Panels” which are peer review groups chosen and managed by an outside scientist.¹⁰²

Typically, a professional elite¹⁰³ conducts the peer review that opines on work product within the discipline. Governmental peer review is not as far ranging as in academia. Industry and academic peer reviewers are used by agencies to vet grant proposals and conduct site visits to university labs.¹⁰⁴ Agencies use peer review, according to the General Accounting Office to: “(1) assess the merit of competitive and noncompetitive research proposals, (2) determine whether to continue or renew research projects, (3) evaluate the results of the research prior to the publication of those results, (4) establish annual budget priorities for research programs, and (5) evaluate program and scientist performance. All of the agencies who use peer review do so to assess competitive research proposals for funding (e.g. NIH and NSF use peer review to award grants for scientific research) having nothing to do with science in policymaking. The methods for conducting peer reviews vary among and within

¹⁰² Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 BERK. TECH. L.J. 1, 26 (1994).

¹⁰³ “Individual agencies define peer review somewhat differently; however, all of the agencies’ definitions or descriptions of peer review contained the fundamental concept of a review of technical or scientific merit by individuals with sufficient technical competence and no unresolved conflict of interest. U.S. GEN. ACCOUNTING OFFICE, PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY, GAO/RCED 99-99 (March 1999), available at <http://www.gao.gov/cgi-bin/getrpt?GAO/RCED-99-99>.

¹⁰⁴ For example, NSF uses 58,000 peer reviewers each year to study 40,000 proposals and submit 250,000 separate evaluations. See NAT’L. SCI. FOUNDATION, REPORT OF THE NATIONAL SCIENCE BOARD ON THE NATIONAL SCIENCE FOUNDATION’S MERIT REVIEW SYSTEM (Sep. 30, 2005), NSB-05-119, available at www.nsf.gov/nsb/documents/2005/0930/merit_review.pdf. See also How We Work, <http://www.nsf.gov/about/how/jsp> (last updated July 15, 2005). See also STRENGTHENING PEER REVIEW IN FEDERAL AGENCIES THAT SUPPORT EDUCATION RESEARCH, CENTER FOR EDUCATION (National Academies Press, 2004); Thomas O. McGarity, *Peer Review In Awarding Federal Grants in the Arts and Sciences*, 9 BERK. TECH. L.J. 1, 15 (1994).

the agencies. For example, the agencies select peer reviewers from academia, private industry, and government and obtain review comments, not only in person during site visits, but by mail, in workshops or a combination of methods.¹⁰⁵ Scientific peer reviewers, however, do not decide policy and, as a general matter, they do not set budget priorities or allocate resources (except as between research proposals). EPA peer reviewers, for example, oversee the scientific research conducted by outside groups for the agency under its Office of Research and Development's \$40 million dollar research budget.¹⁰⁶ They do not necessarily have a voice in decision making.¹⁰⁷ In no instance is an agency accountable to the scientific community.¹⁰⁸

While lawmaking is not under the purview of science, Congress has tried to increase the use of peer review (even as it mandates that agencies reduce the number of Federal Advisory Committees) in agencies to improve the quality of information used and disseminated by them. The Information Quality Act (IQA) legislates that data will be of sufficient quality under the Act and therefore that government will be able to make decisions based on that information if, according to OMB's interpretive guidelines of the IQA, it is subjected to

¹⁰⁵ U.S. GEN. ACCOUNTING OFFICE, PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY, GAO/RCED 99-99 (March 1999), available at <http://www.gao.gov/cgi-bin/getrpt?GAO/RCED-99-99>.

¹⁰⁶ About EPA, <http://www.epa.gov/epahome/aboutepa.htm> (last updated Aug. 24, 2005).

¹⁰⁷ Stephen Johnson, *Junking the "Junk Science" Law: Reforming the Information Quality Act*, 58 ADMIN LAW REV. 37 (2006); see also Michelle V. Lacko, *The Data Quality Act: Prologue To A Farce Or A Tragedy?*, 3 EMORY L.J. 305 (2004).

¹⁰⁸ E. Donald Elliott, *Strengthening Science's Voice at the EPA*, 66 L. & CONTEMP. PROBS. 45, 58 (2003) (It has become a canon of institutional faith at EPA that scientists should just stick to the facts and not make policy recommendations.).

independent peer review.¹⁰⁹ In its Final Information Quality Bulletin for Peer Review, OMB set forth detailed requirements for peer review that focused on “timing of peer reviews, selection of reviewers, transparency of review, and opportunities for public participation.”¹¹⁰ The OMB Guidelines mandate that agencies set up peer review processes and involve the public in them.

This is not a surprising approach since agencies have longstanding experience with peer review practices,¹¹¹ which are, of course, in widespread use in the scientific community. “It is an integral practice to the development of quality research in the private and public sectors, in industry and in education because the process of peer review allows even a large group of scientists, regardless of geographic proximity, to collaborate on the evaluation of innovation.”¹¹² As Robert Reich, former Secretary of Labor, explains, such regularized review processes are well-suited to the workings of administrative agencies: “[T]he postwar intellectual and political project in policymaking became the reconciliation of the practical necessity of broad administrative discretion with this emerging pluralist norm. The “solution” was found in the idea of *administrative process*. Henceforth, public administrators would become managers of neutral processes designed to discover “optimal” public policies.

¹⁰⁹ Office of Mgmt. & Budget, Information Quality Guidelines, 67 Fed. Reg. 369 (Jan. 3, 2002), reissued with corrections, 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002).

¹¹⁰ Stephen Johnson, *Reforming the Information Quality Act*, 58 ADMIN. L. REV. 60 (2005) (quoting Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2671 (Jan 14, 2005)).

¹¹¹ Mohammed Kashef, Scientific Peer Review In The Public Sector (last modified Dec. 5, 2005), available at http://dotank.nyls.edu/communitypatent/peerreview_dec05.pdf.

¹¹² Mohammed Kashef, Scientific Peer Review In The Public Sector (last modified Dec. 5, 2005), available at http://dotank.nyls.edu/communitypatent/peerreview_dec05.pdf.

The hallmark of the administrator became procedural expertise in using a set of techniques applicable to all sorts of public problems rather than substantive expertise in solving particular kinds."¹¹³ As such, peer review represents a fairly conservative means to attack the information quality problem and would seem, at first glance, to provide the much needed oversight and accountability.

In fact, peer review is fraught with problems that undermine its credibility.¹¹⁴ Were it not for the fact that it can be significantly improved upon, it might be caviling to attack governmental peer review, though, leading scientific organizations already have.¹¹⁵ First, let us identify the shortcomings in order to demonstrate the argument that open review presents the better alternative.

¹¹³ Robert Reich, *Public Administration and Public Deliberation: An Interpretive Essay*, 94 *YALE L.J.* 1617, 1619 (1985).

¹¹⁴ SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICY MAKERS* (1990); Wendy Wagner, *The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 *L. & CONTEMP. PROBS.* 63, 67ff. (2003) (criticizing how "good science" reforms attempt to promote greater peer review); Sidney A. Shapiro, *Peer Review and the Politicization of Government Science*, in *RESCUING SCIENCE FROM POLITICS*, (Wendy Wagner, Rena Steinzor, eds., 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=910915.

¹¹⁵ See OMB Watch, *Peer Review News*, available at <http://www.ombwatch.org/article/archive/232> (archive of objections to OMB peer review guidelines). See also *Defending Science*, *OMB's Peer Review Guidelines*, at http://www.defendingscience.org/public_health_regulations/peer_review_guidelines.cfm (last visited Aug. 30, 2006). See also Chris Mooney, *The Politics of Peer Review*, in *Committee for the Scientific Investigation of Claims of the Paranormal* (Jan. 8, 2004), available at <http://www.csicop.org/doubtandabout/peerreview/> ("Given all this, you might expect that a recent White House Office of Management and Budget proposal to expand the use of peer review in the evaluation of scientific research conducted by federal agencies would find a warm welcome from scientists. You'd be dead wrong. Scientific heavyweights like the American Public Health Association, the Association of American Medical Colleges, and the Federation of American Societies for Experimental Biology have issued scathing critiques of the proposal (the latter two jointly), as have a range of other organizations and experts. The hallowed American Association for the Advancement of Science--which publishes the preeminent peer reviewed journal *Science*--also has worries about the idea. A group of Democratic members of Congress even dubbed it a "wolf in sheep's clothing.").

The problems of traditional peer review stem from the fact that it is an elite, closed process and therefore subject to manipulation. Not necessarily closed in the sense of secretive,¹¹⁶ but in the sense that agency peer review groups are empanelled not self-selected. It is therefore possible to stack the deck with ideologues and to create peer review mechanisms that are fraught, not with deliberative disagreement, but unproductive conflict. Because the membership of these groups is closed, the community itself has no say over who participates. Typically, only certain kinds of industry and academic experts will be invited. Those limitations need not be based on politics – though a political litmus test is frequently imposed¹¹⁷ – but may, however, be based on status and thereby shut out otherwise qualified participants with meaningful contributions.

There is no single set of procedures that define peer review. Its practice varies widely across agencies. Hence there are no required mechanisms to ensure transparency in the work of agency peer reviewers. The mere fact that these panels share the name “peer review” with that of rigorous academic counterparts does not ensure the quality of their work (nor that of academic peer review). There are no assurances that what they do is based on good science rather than political prejudice. GAO has found that “further improvements are needed to expand the scope of peer reviews [at EPA] and make them more

¹¹⁶ The purpose of the Federal Advisory Committee Act is to ensure that advice rendered by advisory committees is open and accessible. Federal Advisory Committee Act, Pub. L. 92-463, 5 U.S.C., App 2 6(c) (2) (2006).

¹¹⁷ To serve on the NIH Drug Abuse panel, candidates were asked if they had voted for President Bush. See William R. Miller, *Litmus Test for Appointees at the National Institute on Drug Abuse*, available at http://www.ucsusa.org/scientific_integrity/interference/nih-drug-abuse-panel.html (last updated Aug 10, 2005).

independent," and that the implementation of EPA's peer-review policy has been "uneven."¹¹⁸

Peer review is also time-consuming to organize¹¹⁹ and to run.¹²⁰ Because the group has to be selected, vetted and approved and fights can arise over membership, it is a difficult process. Conflicts of interest have to be identified and sorted out. Participants have to be convinced to join. Not only does the composition of the group need to be selected and defended, but the scope of its work can be contested. Hence, setting up peer review panels requires boundary setting and policing and the defense of those boundaries.

It is, perhaps, in part because of the work that must go into maintaining a peer review system that review generally happens late – too late in the process to have a maximum impact on regulatory decision making. The same complaint is frequently leveled against citizen participation practices more generally.

¹¹⁸ Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, n.24 (2003) ([The] GAO has "identified several weaknesses in EPA's science programs over the years, including (1) the uneven implementation of peer review procedures for EPA's scientific and technical products, (2) gaps in scientific data, and (3) the lack of performance goals and measures that show the environmental results of EPA's science activities.") (quoting U.S. GEN. ACCOUNTING OFFICE, GOVERNMENT PERFORMANCE AND RESULTS ACT: INFORMATION ON SCIENCE ISSUES IN EPA'S PERFORMANCE REPORT FOR FISCAL YEAR 1999 AND PERFORMANCE PLANS FOR FISCAL YEARS 2000 AND 2001, Pub. No. 00-270 ,(2000)).

¹¹⁹ Sidney Shapiro, *Data Quality: The Data Quality Appropriations Rider: New Procedures and Information Disclosure*, Center for Progressive Reform at <http://www.progressiveregulation.org/perspectives/dataQuality.cfm> (last visited August 14, 2006) ("While ensuring high-quality information is a worthy goal, procedural requirements have an important side effect – they slow down the government's capacity to act and, if they are sufficiently burdensome, they can bring government to a standstill. As a result, the benefits of imposing additional procedures have to be balanced against the consequences to the public of delaying agency action.").

¹²⁰ Megan Sever, *Government Peer Review*, GEOTIMES (Nov. 2003), available at http://www.agiweb.org/geotimes/nov03/NN_peerrev.html ("Opponents, however, warn that the standards could paralyze new regulations, especially on issues such as global warming, or air or water pollution, where the risks and benefits are complex, politically charged and potentially costly.")

Agencies ask for public comment once a rule is already written, often allotting the public a short window in which to provide feedback and leaving little room for meaningful change.¹²¹ As Raul and Dwyer comment: “[I]n many cases, end-of-the-line review cannot repair mistakes or omissions made early in the regulatory development process or fill data gaps. Back-end inspection may be able to identify scientific uncertainties, but rarely can it reduce them. The benefits of regulatory science quality control must also be balanced against the potential for peer reviewers to intrude on the policy domain. If determining whether the data and analysis are adequate for regulatory decision making is the problem, then peer review does not solve the problem. It shifts the problem from decision makers to reviewers.”¹²²

But the closed process fits well with the culture and practice of agencies. “By deferring to expertise and asserting it ourselves, we help create a world organized around the pretense that some people, armed and limited by their special knowledge, can be trusted to be in charge.”¹²³ The peer review process arguably shores up this self-proclaimed expertise by lending credibility to the agency’s assertion of expert knowledge. Frug goes on to point out, quoting the moral philosopher, Alasdair MacIntyre, that “‘Bureaucratic Man’ can thrive only

¹²¹ The Administrative Procedure Act provides for a minimum window of 30 days of public consultation. See 5 U.S.C. § 554(d) (2006).

¹²² See Alan Charles Raul and Julie Zampa Dwyer, *Science in the Regulatory Process*, 66 L. & CONTEMP. PROB. 7, 13 (2003).

¹²³ Gerald Frug, *The Ideology of Bureaucracy in American Law*, 97 HARV. L. REV. 1276, 1333 (1984).

if all of us invent a fiction of expertise that assigns to the character of the 'broad-gauged' leader a role that justifies our own powerlessness."¹²⁴

*Part IV: The Open Review Alternative*¹²⁵

We need institutional processes by which to overcome the problems of closed peer review and create more transparent mechanisms that bring scientific expertise to bear earlier in the process. We have witnessed how the combination of open technology and well-defined process has enabled Wikipedia to elicit the wisdom of the crowd and led to the creation of an encyclopedia with over 1,000,000 entries of quality comparable to that of traditional encyclopedias with centralized editors.¹²⁶ New technology has enabled Amazon to create a marketplace, not just for the sale of goods and services, but also for the aggregation of expertise and recommendations about those goods and services.¹²⁷

CNet offers a platform to broker expertise about electronics and technology. The

¹²⁴ Gerald Frug, *The Ideology of Bureaucracy in American Law*, 97 HARV. L. REV. 1276, 1333 (1984).

¹²⁵ For a complete description of the Peer to Patent proposal, please see Beth S. Noveck, *Peer to Patent*, 20 HARV. J. L. TECH. ____ (2006); see also Nicholas Varchaver, *Patent Review Goes Wiki*, FORTUNE MAGAZINE, Aug. 21, 2006, at 18, available at http://money.cnn.com/magazines/fortune/fortune_archive/2006/08/21/8383639/index.htm?source=yahoo_quote.

¹²⁶ See Wikipedia, at <http://www.wikipedia.org> (as of this writing, there are 1,312,000 entries). See Jim Giles, *Internet Encyclopaedias Go Head To Head*

Jimmy Wales' Wikipedia Comes Close To Britannica In Terms Of The Accuracy Of Its Science Entries, A Nature Investigation Finds, NATURE (Dec. 14, 2005; updated March 28, 2006) (revealing that study by Nature demonstrates that Wikipedia is about as inaccurate as Encyclopedia Britannica).

¹²⁷ See Shay David and Trevor Pinch, *Six Degrees of Separation: The Use and Abuse of Online Review and Recommendation Systems*, FIRST MONDAY (March 2006) (describing strategies and techniques of user reviews and recommendations on Amazon).

Internet Movie Database, the largest repository of information about cinema, is created by volunteers submitting data about films and movie stars.¹²⁸ Public Library of Science, the pioneering open access publisher of scientific journals, is launching PLoS One, a distributed knowledge network to enable scholars of biology and medicine to discuss published research literature.¹²⁹ We are learning as a result of these experiences with online collaboration that often “ordinary” people possess extraordinary knowledge they are willing to share when it is easy to do.¹³⁰ This peer-production of content works well online.¹³¹ By making participation open and subject to self-selection, we can leverage, not only the wisdom, but also the enthusiasm of the crowd.¹³² Experience with the tools now available is undermining traditional assumptions about how expertise must be organized and pointing the way toward open models of scientific review, not

¹²⁸ Internet Movie Database, available at <http://www.imdb.com>. See also Internet Movie Database entry on Wikipedia, available at <http://en.wikipedia.org/wiki/IMDB> (“The IMDb website consists of the largest known single accumulation of data on individual films (including complete cast and crew listings), television programs (including complete cast and crew listings), direct-to-video product and videogames reaching back to their respective beginnings, and worldwide in scope... Information is largely provided by a cadre of volunteer contributors, with only 17 members of the staff dedicated to monitoring the data received) (last updated Aug. 15, 2006).

¹²⁹ http://www.plos.org/news/announce_plosone.html

¹³⁰ Yochai Benkler, *Freedom in the Commons: Towards a Political Economy of Information*, 52 DUKE L.J. 1245, 1256 (2003) (stating that peer production is the collaborative process by which individuals “contribute to a joint effort” to produce “information or culture”).

¹³¹ ¹³¹ See Yochai Benkler, *Coase's Penguin, or, Linux and The Nature of the Firm*, 112 YALE L.J. 369 (2002) (discussing collaboration in the context of open source, and other peer-review projects).

¹³² JAMES SUROWIECKI, *THE WISDOM OF THE CROWD* (2004) (demonstrating how groups of people can be smarter and more effective at certain kinds of decisions than individuals).

only to create encyclopedias or book reviews,¹³³ but also – and this is the radical proposal – to inform legal decision making.

First, we will outline how an open peer review process for patent examination could work and then, we will discuss the advantages of such a change for the way the agency operates. The goal is not to outline technical details of the policy proposal but to illuminate the normative and practice desirability of openness by reference to some of the key design features.¹³⁴ If we are to succeed in lobbying for a move away from peer review and toward open review, we need to demonstrate exactly how it addresses the problems of a closed system.

The proposed system for open review directly addresses the problems with the current examination process, including the “goldilocks dilemma” by enabling the community of practice to collaborate on finding prior art, evaluating the application and transforming the “person skilled in the art” from a fictional

¹³³ MediaCommons, a new endeavor from the Institute for the Future of the Book, will involve communication studies scholars in real-time open peer review, see Kathleen Fitzpatrick, *Introducing MediaCommons* http://www.futureofthebook.org/blog/archives/2006/07/introducing_mediacommons_or_ti.html (July 17, 2006).

¹³⁴ There are existing examples of patent commentary websites, though these are not linked to Patent Office decision making. See Prevalent.de Software Patents, available at <http://prevalent.de/index.pl?site=1&subsite=3&lang=en>. See also CAMBIA Patent Lens, which offers patent searching and will eventually offer annotation, available at <http://www.patentlens.net/daisy/patentlens/patentlens.html> (“The Patent Lens contains patent documents from the European and United States patent offices and filed under the Patent Cooperation Treaty (PCT) in a format that is fully integrated and searchable. The Patent Lens also offers technology landscapes, which describe key areas of plant biotechnology and the patent claims surrounding them. In addition you will find patent tutorials, information on patent policies, and news and views in the world of IP.”) See also PatentWiki, <http://www.patentwiki.org>.

legal personage into a real group.¹³⁵ This system augments review by the lone examiner with assistance from experts in the relevant art area, revolutionizing the way patents are examined and providing a model for expert participation in regulatory decision making.¹³⁶ The United States Patent and Trademark Office has adopted the proposal as part of its Strategic Initiatives and will launch a pilot of open review in 2007.¹³⁷ The European Patent Office (EPO) is considering following suit. The project has captured the imagination of some of the world's largest and most active patent holders, who have agreed to let some of their own patents be reviewed openly. These include: IBM, Microsoft, Oracle, Intel, Hewlett-Packard and Red Hat.

It is illogical to have one person – with access to limited information – determining originality¹³⁸ and whether the inventor slept on his rights¹³⁹ as well as

¹³⁵ For related earlier proposals pertaining to patent bounties, see John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305 (2001) (arguing that awarding prior art informants with a bounty assessed against applicants, the Patent Office can restore order to the patent system and reduce its social costs.); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERK. TECH L.J. 667 (2004). See also Michael Felton, *A Call for Bounty Hunters, in Patents and Property* (March 2001), available at <http://pubs.acs.org/subscribe/journals/mdd/v04/i03/html/03patents.html>.

¹³⁶ ADAM B. JAFFE AND JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* 22 (2005) (“Until the process is changed so that other parties that know something about the technology surrounding a given application have the opportunity and incentive to bring that knowledge forward, there will be no cost-effective way to fix the problem of low quality patents.”).

¹³⁷ See U.S.P.T.O. Draft Strategic Plan 2007-2012, 71 Fed. Reg. 50048 (2006), available at <http://www.uspto.gov/web/offices/com/strat2007/index.htm>.

¹³⁸ 35 U.S.C. § 102 (2004) (novelty).

¹³⁹ *Egbert v. Lippmann*, 104 U.S. 333, 337 (1881) (“The invention, forming the springs of corsets of two or more metallic plates, placed one upon another, and so connected as to prevent them from sliding off each other laterally or edgewise, was completed and put to use in 1855. The inventor slept on his rights for eleven years. Letters-patent were not applied for till March, 1866.”).

obviousness¹⁴⁰ or even enablement¹⁴¹ when we can harness the collective intelligence and experience of thousands. Many technological advances are not described in commonly available academic publications or those sources to which the patent examiner has easy access. It is also illogical to turn to a single firm, as the Patent Office once suggested, to conduct this review when those with the deepest experience in any given area of innovation and bring their expertise to bear.¹⁴²

The pilot will focus on creating an online system to assist with novelty review by allowing for the submission of prior art. The novelty determination is ideally-suited to peer review because it enunciates a clear goal, requires only minimal participation to address and lends itself to self-selection on the basis of expertise.¹⁴³ Far better for me to designate what I am good at since I am in the best position to know.¹⁴⁴ While a patent examiner might have to search for prior art for hours, an expert knows instantly whether an invention is reminiscent of earlier work or avenues of research. Designed right, the software can make participation for a network of scientific and innovation experts clear and easy.

¹⁴⁰ 35 U.S.C. § 103 (2004) (non-obviousness).

¹⁴¹ 35 U.S.C. § 112 (2004) (enablement).

¹⁴² USPTO, *The 21st Century Strategic Plan* (2003) (To achieve greater examiner productivity by reducing their prior art search responsibilities, the USPTO is looking at market driven examination options.) at <http://www.uspto.gov/web/offices/ac/comp/proc/pctsearch/pctsearchhom.html> (last visited Sept. 30, 2005).

¹⁴³ See STEVEN WEBER, *THE SUCCESS OF OPEN SOURCE* 62 (2004) (“The key element of the open source process, as an ideal type, is voluntary participation and voluntary selection of tasks.”).

¹⁴⁴ See GUIDO CALABRESI, *THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* (1970) (Calabresi discusses the notion that the entity in the best position to carry the “burden” is the one that should.).

As Eric Raymond, hacker “anthropologist” phrased it, with many eyeballs “all bugs are shallow.” Just as a community of open source programmers is well-suited to spotting mistakes in code, the peer to patent community is equipped to address whether an invention is novel or resembles something seen before. A prior art novelty review is an opportunity to get more public input into the patent system and introduce citizen consultation, the common and required practice of every government agency,¹⁴⁵ into the intellectual property review process.¹⁴⁶

Once an application is published to the Web (under current rules, this happens at eighteen months,¹⁴⁷ though an applicant can consent to earlier publication),¹⁴⁸ it can be pushed out to the relevant experts. Using RSS (really simple syndication)¹⁴⁹ those with an interest in a particular area of art, whether it

¹⁴⁵ Administrative Procedure Act §1, 5 USCS § 553 (b) (1946) (General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law.) *See also*, 5 USCS § 553 (c) (1946) (After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.). On the application of administrative law to the patent system, see Stuart Benjamin and Arti Rai, *Who's Afraid of the APA? What the Patent System can Learn from Administrative Law*

¹⁴⁶ USPTO, *The 21st Century Strategic Plan* (2003) (To achieve greater examiner productivity by reducing their prior art search responsibilities, the USPTO is looking at market driven examination options, including outsourcing prior art review to private firms) at <http://www.uspto.gov/web/offices/ac/comp/proc/pctsearch/pctsearchhom.html> (last visited Sept. 30, 2005).

¹⁴⁷ 37 C.F.R. § 1.211 (2006).

¹⁴⁸ 37 C.F.R. § 1.219 (2006).

¹⁴⁹ While the Patent Office does not offer syndication, a private website, Fresh Patents does. See <http://www.freshpatents.com> (last visited October 19, 2005). See also *Introduction to RSS*, (revised April 14, 2003) (Really Simple Syndication (RSS) is an XML format designed for sharing headlines and other Web content. RSS defines an XML grammar for sharing content. Each RSS text file contains both static information about a

is class 482 Exercise Devices or class 438 Semiconductor Device Manufacturing,¹⁵⁰ can receive notification of the name and abstract of any new inventions filed via newsreader, email or mobile phone for initial review. This makes it simple, not only to learn about published applications, but also to share that information with others since it is the expert in the community of practice who will know who and how to find the other experts with knowledge of a particular area of art.

Information visualization tools make it simpler to evaluate the volume of information and the frequency of communication to facilitate participation. Visualization aids will make it easier for a subscriber – whether it is an industry or academic scientist, a graduate student or professor or a competitive inventor and her lawyers – to see the quantity of applications historically published in each class and sub-class in order to know how broadly to subscribe and avoid being overwhelmed. One needs to know in advance that Class 514 Drug, Bio-Affecting and Body Treating Compositions, is the most populous class, and that one ought to sign up for relevant sub-classes, or that Needle and Pin Making received only 1 application last year.

The system will promote “lonely patents” by advertising under-subscribed patent classes and subclasses for review to the network of experts. It might employ a collaborative filtering system akin to Amazon’s to suggest

website or weblog, plus dynamic information about new stories, all surrounded by matching start and end tags) at <http://www.webreference.com/authoring/languages/xml/rss/intro/> (last visited Sept. 30, 2005). For more about the use of RSS in government, see <http://www.rssgov.com> (last visited December 5, 2005).

¹⁵⁰ The Patent Classification System can be found online arranged alphabetically, by subject matter, by class number and by art unit. See, Patent Classification System, <http://www.uspto.gov/web/offices/opc/>.

patents to review (e.g. “people who submitted prior art for this patent also read that patent.”). Experts will receive RSS or email notifications of patents for which no prior art has yet been submitted. Reviewing one patent application will generate a prompt: “Would you like to review another?” Again, if the system is designed to optimize inputs and facilitate participation, it can reduce the burden of reviewing a patent for novelty and commenting on prior art.

In addition, reviewers can “tag” or label applications, not only according to the official classification taxonomy, but also by their own designations. This kind of supplementary community self-tagging – or what is sometimes called a “folks-onomy”¹⁵¹ – might make it easier to find applications of interest by allowing experts to apply other labels to identify an invention in the terminology that is common to his or her specialty. In other words, what the patent office calls Exercise Devices, may commonly be known among physical therapists as elliptical machines. What the Patent Office might refer to as semi-conductor manufacture, the reviewer might also label “chip.” Such a folksonomy could make labeling more granular and precise to speed up the process of self-assignment.¹⁵² We already have tagging and labeling software, most commonly

¹⁵¹ For more on folksonomies, see Wikipedia, <http://en.wikipedia.org/wiki/Folksonomy> (last updated January 1, 2006). See also, Clay Shirky, *Ontology is Overrated: Categories, Links, and Tags*, at http://www.shirky.com/writings/ontology_overrated.html (last visited January 2, 2006).

¹⁵² “Zoo Bank” is creating just such a user-created taxonomy and classification system in another arena. The technique and the technology could be used to classify inventions. See *Commentary: A Universal Register for Animal Names*, 437 NATURE 477 (Sep. 22, 2005). The Open Source Development Lab has launched the “Open Source Software as Prior Art” project which aims to use tagging to make open source software more available to patent examiners (“The goal is to reduce the number of poor quality patents that issue by

known from photo-sharing services such as Flickr, that allows Internet users to label content for easier retrieval, indexing and searching.¹⁵³

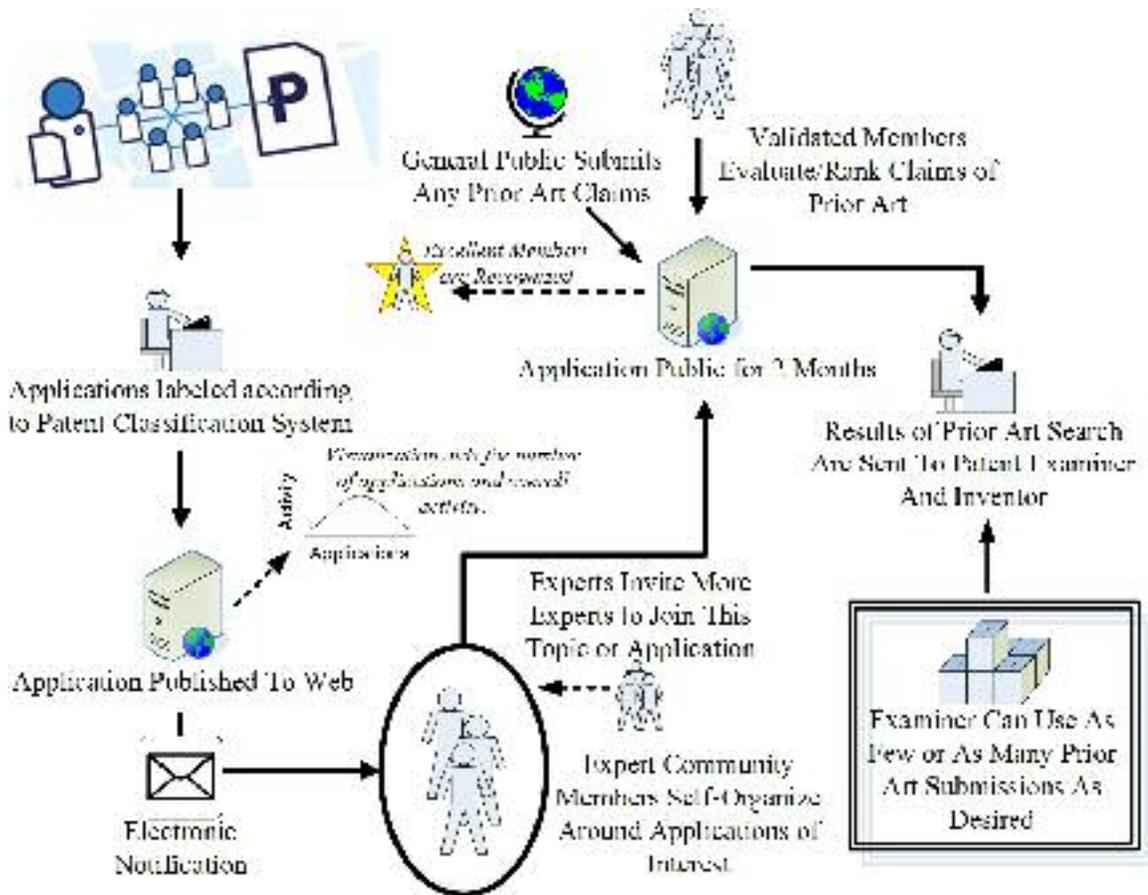


Figure 1 - Open Review Pilot Process

Each application will reside on a web page where members of the community of practice and interest can submit relevant prior art for a two-month

increasing accessibility to Open Source Software code and documentation that can be used as prior art during the patent examination process. For the Open Source community and many others, this means a reduction in the number of software patents that can be used to threaten software developers and users, and a resulting increase in innovation.”), available at <http://developer.osdl.org/dev/priorart/>.

¹⁵³ See del.icio.us About Page, <http://del.icio.us/doc/about> (last visited Sept. 30. 2005).

window after publication.¹⁵⁴ Two months tracks the amount of time currently available to members of the public wishing to submit prior art under CFR Rule 1.99¹⁵⁵ (though this could just as well be three or four months). Rule 1.99 provides that third parties can submit prior art within that two month window and after paying a fee. To enable prior art peer review, as we are describing here, the Patent Office, at least initially, has agreed to waive the filing fee of \$180 to facilitate submission of art.

More significantly, two months creates a manageable window of time in which to learn about and submit prior art without overwhelming the examiner or the community with too much data to review. By delimiting the time for submission of prior art, this could aid the examiner while drastically accelerating the process of review from the average 2-4 years¹⁵⁶ that the Patent Office currently requires. By speeding up the review process, we also speed up the

¹⁵⁴ There once existed a private service known as BountyQuest where inventors could post an application and pay for third parties to submit prior art as a mechanism to strengthen the quality of the application and find any prior art before the fact. See Sabra Chartrand, *Patents: Disproving Idea Ownership*, N.Y. TIMES, October 23, 2000, available at <http://www.nytimes.com/2000/10/23/technology/23PATE.html?ex=1143262800&en=b13756e07e50dd38&ei=5070>. See also John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 307 (2001) (proposing “that the Patent Office recruit members of the public to act as private patent examiners. By awarding prior art informants with a bounty assessed against applicants, the Patent Office can restore order to the patent system and reduce its social costs.”)

¹⁵⁵ 37 CFR § 1.99 (2004).

¹⁵⁶ See U.S.P.T.O. Draft Strategic Plan 2007-2012, 71 Fed. Reg. 50048 (2006), available at <http://www.uspto.gov/web/offices/com/strat2007/index.htm> (Patent pendency now averages more than 30 months and is expected to increase to 33.8 months (to issue) in 2011). In some areas, patent pendency is as high as 43.5 months. See http://www.uspto.gov/web/offices/com/annual/2005/060404_table4.html (2005).

time for scientists to publish and publicly discuss innovation without the fear of triggering a statutory bar.¹⁵⁷

To submit prior art, a member of the community will log onto the system. That logon need not be verified or even persistent. We want a small hurdle to prevent junk from being submitted but not so high a hurdle as to create a stumbling block to participation. At this stage of the game, the Patent Office ought to want good prior art from anywhere and anyone who has it. It does not matter if the party is interested or dispassionate. In fact, competitive interest will be a driver and incentive to finding relevant prior art and participating in the system.

The design of the system will enable the community to designate the claims that are the crux of the invention. An application might recite a method for sending and receiving electronic signals by means of a special hash algorithm. The examiner does not need prior art pertaining to sending and receiving, which are common steps. Rather, the Community's attention should be directed to finding prior art pertaining to the hash algorithm. If the community identifies the central claims, there is a role to play, not only for scientists, but also for lawyers as stewards of this process that mixes knowledge of law with a knowledge of science.

Second, directions, instruction and even moderation by members of the community are essential at every step in the process to create a strong ethos of

¹⁵⁷ 35 U.S.C. §102 (b); 35 U.S.C. §102 (e); (Section contains three different patent bars; the "printed publication" bar, the "on-sale" bar, and the public use bar. *See also*, *Midland Flour Milling Co. v Bobbitt*, 70 F.2d. 416 (1934) (holding prior publications rest upon same ground as prior patents so far as anticipation is concerned and no valid patent can be obtained if invention or device is disclosed in printed publication.)

community and encourage the submission of useful and appropriate materials. Wikipedia uses various mechanisms from written directions to open community peer review and deletion to warning labels¹⁵⁸ to ensure that entries posted are, in fact, appropriate for an encyclopedia and adhere to standards of quality. The Wikipedia community has evolved a clear and explicit sense of its mission and a set of rules for writing encyclopedia entries. Similarly, a peer review system for patents has to make very clear to participants what is expected of them. The software itself will reject entries without references or sources or with a prior art date that post-dates the invention. But the community itself can play a role by voting good prior art up and irrelevant submissions down.

Third, the interface will be designed to require a submitter to identify the claim to which a piece of prior art pertains.¹⁵⁹ This will make participation easier to review and more manageable for the examiner by allowing him to winnow out prior art that relates to claims about which he needs no information. It also makes it easier, especially for a patent with dozens of claims, for the examiner and the community to assess the relevance of that submission. "This article invalidates claim 3" is more useful than "this article invalidates this patent."

¹⁵⁸ Katherine Mangu-Ward, *The Neutrality of this Article is Disputed*, REASONONLINE (Aug 15, 2006), available at <http://www.reason.com/links/links081506.shtml> ("early every Wikipedia user has occasionally come across a little tag at the top of an article: "Stop!" it says, "The neutrality of this article is disputed. Please see the discussion on the talk page." This little tag, I'm convinced, is the secret to Wikipedia's success. And I'm not alone).

¹⁵⁹ In the search report filed by an examiner performing a review under the PCT (Patent Cooperation Treaty), the examiner cites prior art with the appropriate and relevant passages noted, indicates the claim to which such prior art speaks and labels the submission with one of 9 codes, including X, Y or A where X stands for novelty, Y stands for obviousness and A stands for general state of the art. See International Search Report Model Form at U.S.P.T.O., PARTS, FORM, AND CONTENT OF APPLICATION, MANUAL OF PATENT EXAMINING PROCEDURES (MPEP) §1844.01 (8th ed. 2004).

Fourth, as on Slashdot where peers moderate each other's postings in order to enable readers to filter out quality comments as adjudged by the community, members of the peer to patent community should rank the prior art for relevance. The output at the end of the process will be a rank-ordered list of prior art, identifying the top ten submissions as judged by the community. Participation might require a minimum of three ratings. Incentives can be built into the software, as Slashdot does,¹⁶⁰ to encourage ongoing rating and ranking. This has the effect of winnowing the submissions and making them more useful and manageable to the examiner. The examiner will still have access to the full list, which he can search, as he would any database, but, in this case, the database will have been ordered not by machine but by people with relevant expertise.

Finally, earlier experience with peer review systems teaches that participation will be enhanced through status and reward. Members of the community who post useful information will receive "karma effects,"¹⁶¹ status points for submitting prior art that is deemed relevant by the community.¹⁶²

¹⁶⁰ The Slashdot news site allows its members to rate postings in order to enable other members to sort content based on member reviews. Good information, as determined by that community and within the context of its own culture and values, rises to the top. See Slashdot Comments and Moderation FAQ at <http://slashdot.org/faq/com-mod.shtml> (last visited Aug. 15, 2006).

¹⁶¹ For more on the role of status and reputation in fostering collective action, see Paul Resnick et al., *Reputation Systems*, 43 COMMUN. OF THE ACM 45, 46 (Dec. 2000); See also Peter Kollock, *The Production of Trust in Online Markets*, in 16 ADVANCES IN GROUP PROCESSES (E.J. Lawler, M. Macy, S. Thyne & H.A. Walker eds., 1999); Paul Resnick, *Impersonal Sociotechnical Capital, ICT's, and Collective Action Among Strangers*, in TRANSFORMING ENTERPRISE: THE ECONOMIC AND SOCIAL IMPLICATIONS OF INFORMATION TECHNOLOGY 399, (William H. Dutton, Brian Kahin, Ramon O'Callaghan & Andrew Wyckoff, eds., 2004).

¹⁶² There are numerous existing social reputation software systems. Some of these websites focus on social or dating relationships and offer rating systems whereby people are "rated" based on who they know and who their friends are. In other words, the wildly popular Friendster or Orkut provide a graphical map of my friendships. Cyworld,

Status and reputation are essential to building the trust in the community necessary for iterative interaction.¹⁶³ It is also crucial for determining qualifications for participation and for creating an incentive to ongoing collaboration. The currently prevailing wisdom is that social reputation software and other automated mechanisms for according status is the way to foster and find such expertise. Reputation points on EBay, karma points on Slashdot, honorifics in academic circles, all of these status mechanisms create an incentive to participation and help to inculcate norms within the group. The peer patent review system will also need to evolve mechanisms of conferring status on those people who participate well and shoulder their burden.¹⁶⁴ Reputation points help to encourage active participation. It might come to be an important part, for example, of being a graduate student in a field or being a junior scientist in a corporation working in a particular area of art. One gets rewarded for

another social networking service boasts a quarter of the population of Korea as its user base. Linked In provides such a map for my business relationships. Epinions bills itself as a “web of trust” system. It allows me to create a network of trusted reviewers. Slashdot moderates its site based on similar principles. The community decides which contributors and content is best and that information rises to the top. Virtual worlds, like Second Life, have a social reputation system based on interactions between players. Kuro5hin which uses mojo to allow users to moderate the site. Mojo is a time-weighted average of comment ratings, in order to set the “initial” rating for each new comment. Time spent with another player indicates friendship. New publishing models also rely heavily on social reputation software to filter content. Outfoxed is a service that “uses your network of trusted friends and experts to help you find the good stuff and avoid the bad” by using social reputation as a criterion in web surfing. There is already a wide variety of social reputation tools even though we are just at the beginning of their evolution and are sure to see the development of a wide new array of technological structures designed to measure social reputation. See Beth Simone Noveck, *Trademark Law and the Social Construction of Trust: Creating the Legal Framework for On-Line Identity*, 84 WASH. U. L. Q. __ (2006).

¹⁶³ See Beth Simone Noveck, *Trademark Law and the Social Construction of Trust: Creating the Legal Framework for On-Line* 84 WASH. U. L. Q. __ (2006) (arguing that reputation systems are crucial to fostering trust in online environments).

¹⁶⁴ See Paul Resnick et al., *Reputation Systems*, 43 COMM’N. OF THE ACM (Dec. 2000).

submitting art deemed relevant by the community and even more points for art that is eventually used in the final determination by the examiner. By tying status to relevance, the institution of online peer review can encourage, not only participation per se, but better quality participation and the submission of art that is useful and practical.

Part V: Why Open Review

The open review system being constructed by the USPTO allows: 1) submission of prior art and commentary in response to the pending application of a consenting applicant; 2) where the community identifies the claims that are most relevant; and 3) directions and tutorials create a strong ethos of community and a clear indication about how to participate; and 4) participation is chunked into manageable tasks, including the rating and ranking of other people's postings in order to produce a manageable top 10 list of prior art submissions; and 5) successful participation, as determined by an examiner's use of submitted prior art, generates positive reputation points. This, in short, is the outline of an open system that overcomes the problems of closed peer review while providing more information into the decision making process in a manageable form.

The advantages to open review are myriad and we will discuss each one of these in turn. In sum, it:

- Eliminates the institutional and status boundaries of expertise
- Reduces the work of administering peer review or public participation and potentially accelerates decision making

- Improves decision making for the better by opening up the flow of information while making it manageable
- Makes government more accountable to science
- Ensures that decisions comport with scientific fact
- Will not only make more science available, it will reveal debates over that science
- Introduces information into the process early
- Obviates the need to await litigation to challenge the basis of decision making
- Promotes deliberation around issues of national importance
- Increases oversight over the regulatory process
- Is more expert and more participatory

"When a handful of distinguished gentlemen came together in post-Restoration England to set up the Royal Society, they agreed that membership should be open only to the better sort. Allowing tradesmen and artisans to join the collective search for truth seemed too dangerous to be tolerated, for, after all, the worldly interests of such people might corrupt their decisions about what counted as genuine knowledge."¹⁶⁵ Open review abandons this now-outdated vision of expertise. In so doing, it can eliminate the problems of lack-of-transparency and manipulation that plague closed peer review panels because it opens up the process via the Internet, allowing peer reviewers to self-select, rather than to be selected. If the aim is to get at good prior art, it does not matter

¹⁶⁵ PHILIP KITCHER, *SCIENCE, TRUTH AND DEMOCRACY* 29 (2001).

where it comes from so long as it is provided. Often, the best wisdom comes, not from the center, but from the periphery among the enthusiasts and hobbyists or from graduate students who are immersed in but not yet well known for their knowledge of the discipline. Opening up review also reduces the burden on any one group of people over time by increasing the number of people potentially engaged in the process.

In addition, opening up the process and eliminating closed boundaries not only introduces more and better information from new sources, but it also exercises a self-policing effect. Participants are not constrained by professional allegiances nor do they become entrenched in the culture and practices of a small, closed group. Scholarly debates are open playing-fields where everyone participates in a common conversation. Similarly, an open system for science in policymaking would provide greater accountability among scientists to each other, regardless of whether they are in academia, industry or the public sector.

While there is an up front cost to setting up the software and the processes by which open review will be conducted, it minimizes the workload after the fact. There is no need to empanel juries or to police their boundaries. As in the "Peer to Patent" system, the software can do the work of rating and ranking participants and promoting the best submissions, as decided by the community, to the front of the queue for consideration. If the work to be done is made as granular as possible, it further reduces the workload by allowing more people to participate for less time.

It will potentially improve decision making by opening up the flow of information from the public and from the scientific community while, at the

same time, leveraging technology to make that flow manageable for participants and government officials alike. The Peer to Patent Proposal¹⁶⁶ suggests transmitting only the top 10 items of prior art, as identified by the community, to the patent examiner. We need to start exploring ways to embed procedure into software in order to make public participation practicable and in order to let the community itself participate in vetting the quality of information.

Having such processes readily deployable will make it possible to render government more accountable to the scientific community and to integrate legal and scientific considerations. It is possible and desirable, not to eliminate the patent examiner, but to create a dialogue between the process of scientific fact-finding and legal fact-finding. Given that in the U.S. Patent Office (unlike Europe) most examiners possess only an undergraduate degree in a science (and not necessarily related to the area in which they examine) and that in other agencies, “very few of the participants in the policymaking dialogue at high levels within the Agency were scientifically trained,”¹⁶⁷ open review integrated into the decision making process creates mechanisms to inform the work of the bureaucrat. Organizing the voice of science places added pressure on agencies to make accountable decisions. It also reduces the risk of manipulation of science by the agency.

Trying to separate science from law, as we have tried to do for so long, is self-defeating. Science and policy are inextricably linked and should be. We

¹⁶⁶ Peer to Patent proposal, please see Beth S. Noveck, *Peer to Patent*, 20 HARV. J. L. TECH. ____ (2006), available at <http://dotank.nyls.edu/communitypatent/proposals.html>.

¹⁶⁷ DAVID SCHOENBROD, *SAVING OUR ENVIRONMENT FROM WASHINGTON* 210 (2005) (quoting E. Donald Elliott, former EPA general counsel).

need the mechanisms by which to let both areas of expertise inform but not confuse or corrupt the way we make policy. We want to guard against regulatory capture while, at the same time, harnessing collective expertise to advance the public interest. “If told that it is improper to make policy recommendations, scientific groups are much more likely to smuggle in their policy predilections covertly, either consciously or unconsciously. We would be far better advised to invite scientific advisory bodies to separate their scientific conclusions from their policy recommendations, and to empower them to address both.¹⁶⁸

The way to do this is by opening the process.

David Schoenbrod tells of an example where scientists and physicians ripped to shreds the EPA's report on lead pollution that suggested levels of lead pollution were safe.¹⁶⁹ The report did not comport with scientific fact. Open review creates a way to address whether something is technologically feasible as a matter of scientific fact (which may be a different question from whether it is economically prudent).¹⁷⁰ It lets the patent examiner know if there is, in fact, a similar invention already invented or if his assessment of whether a particular substitution of compound X for compound Y is really not obvious.

But open review not only makes more science available, it can reveal debates over that science. “Good science is a chorus of independent expert voices that come together with sufficient coherence and force to constrain policy, structure debate, and influence policy. Rarely does good science dictate a unique

¹⁶⁸ E. Donald Elliott, *Strengthening Science's Voice at the EPA*, 66 L. & Contemp. Probs. 45, 58-59 (2003).

¹⁶⁹ DAVID SCHOENBROD, *SAVING OUR ENVIRONMENT FROM WASHINGTON* 32 (2005).

¹⁷⁰ DAVID SCHOENBROD, *SAVING OUR ENVIRONMENT FROM WASHINGTON* 40 (2005).

policy outcome; more often, it structures a policy dialogue among different disciplines and constituencies by defining a problem and a range of options, but it may also figure in the decision of which options to adopt."¹⁷¹ A more open and deliberative dialogue about science eliminates the concerns to which closed peer review is prone, namely the fear that there may not be scientific consensus around an issue. When we discuss whether an innovation is truly novel and non-obvious, there may be disagreement. Airing that disagreement is helpful to the process and informs how the examiner should proceed – how much time to invest and the course to adopt – in doing his work.

This is also way to challenge bad science much earlier in the process without having to wait for litigation.¹⁷² Reform proposals abound¹⁷³ to change the standard of judicial review for granted patents as well as for agency determinations based on science.¹⁷⁴ Scholars and practitioners have recognized

¹⁷¹ E. Donald Elliott, *Strengthening Science's Voice at the EPA*, 66 L. & Contemp. Probs. 45, 46 (2003).

¹⁷² See, e.g. Joseph Farrell and Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERK. TECH. L. J. (2004).

¹⁷³ See, e.g., Mark A. Lemley, Douglas Lichtman and Bhaven Sampat, *What to Do about Bad Patents?*, 28 REGULATION 10-13 (2005-6) (proposing 1) weakening the presumption of validity, 2) allowing legitimate inventors to earn a presumption of validity and "gold-plating" their patents by paying for more thorough searches, and 2) instituting post-grant opposition, "a process by which parties other than the applicant would have the opportunity to request and fund a thorough examination of a recently issued patent.").

¹⁷⁴ For a discussion of a wide variety of reform proposals, see Matthew Sag and Kurt Rohde, *A Differential Impact Analysis of Patent Reform* (draft dated Aug 12, 2006) (analyzing patent reform proposals through differential impact analysis), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/sag.doc>. See also Brendan Chase, *IBM Calls for Patent Reform*, ZDNET, AUSTRALIA, 11 April 2005, available at <http://www.zdnet.com.au/news/0,39023165,39187609,00.htm>.

the problems that arise with *Chevron*-deference to agency decision making.¹⁷⁵ While this does not substitute for such reforms, open review does provide an additional check – and one more expert than the courts – of the work of agencies.

Open review has another benefit that goes beyond the immediate process of patent examination. It promotes deliberation around issues of national importance. “Such deliberation can lead individuals to revise opinions (about both facts and values), alter premises, and discover common interests. Disagreements and inconsistencies encourage individuals to balance and rank their wants. The discovery that solely personal concerns are shared empowers people to act upon them. Thus, public deliberation helps transform individual valuations into social values; it helps forge collective purposes, and, even more important, helps define and refine public morality. Through such deliberations, individuals become *citizens*.”¹⁷⁶ Engaging the entire scientific community in legal decision making that is affected by science, promotes science education and literacy.¹⁷⁷ On the one hand, this benefits science and advances its role in our society. On the other hand, it puts scientific knowledge to work for larger public purposes by involving the public in peer review. This democratizes the

¹⁷⁵ *Chevron U. S. A. V. Natural Resources Defense Council, et al.*, 467 U.S. 837 (1984) (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations “has been consistently followed by this Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations.”)

¹⁷⁶ Robert Reich, *Public Administration and Public Deliberation: An Interpretive Essay*, 94 *YALE L.J.* 1617, 1631-2 (1985); also Beth Simone Noveck, *Designing Deliberative Democracy in Cyberspace: The Role of the Cyber--Lawyer*, 9 *B.U. J. SCI. & TECH. L.* 1 (2003).

¹⁷⁷ PHILIP KITCHNER, *SCIENCE, TRUTH AND DEMOCRACY* 142 (2001).

conversation about science, promotes deliberation about issues of scientific understanding and advances the goals of democratic participation.

This open process obviously increases oversight over the regulatory process by another institution in addition to Congress and the courts. It allows the public not only to vet but to produce the information on which regulatory decisions are based. In the case of patent examination, this is essential. The centralized examiner does not have access to the requisite information or know-how to make informed decisions. Open review could be used, not only to help the federal bureaucrat do his work, but also to provide the mechanism by which to coordinate more regional processes of decision making and feedback and to spur a conversation across levels of government.

Finally, open review is at once both more expert and more participatory than peer review. It opens up the policymaking process to more members of the scientific community and provides the platform by which to organize and evaluate their input. This suggests a way forward that balances expertise with accountability, science with democracy.

Conclusion: Institutional Competence and Patent Reform

Neither the Patent Reform Act of 2005 nor the Patents Depend on Quality Act of 2006 has passed. While the Supreme Court heard several patent appeals this year, it changed its mind and overturned its own grant of certiorari in *LabCorp v. Metabolite* as improvidently granted.¹⁷⁸ Had it moved forward, this

¹⁷⁸ 584 U.S. ____ (2006).

case would have gone to the central question of the scope of patentable subject matter.¹⁷⁹ Patent reform has been incremental at best with no major changes to the system since the Patent Act was enacted in 1952. Open peer review presents an alternative avenue for legal reform by enhancing the institutional competence of the Patent Office. It focuses on the institution that makes the decisions and employs the new communications practices that technology makes possible to improve its work. Instead of seeking reform through the slower mechanism of judicial review,¹⁸⁰ this proposal addresses its administrative law antecedents by revolutionizing the process of patent examination itself.¹⁸¹

¹⁷⁹ A number of scholars have called for urgent reform of the scope of patentable subject matter and have despaired of its failure to be enacted. For examples of the most recent scholarship, see, Kevin Emerson Collins, *Propertizing Thought* (2006); Eileen Kane, *The Dormancy and Revival of the Patentable Subject Matter Doctrine* (2006); Sean M. O'Connor, *Using Science & Technology Studies to Redefine Patentable Subject Matter under the Progress Clause of the Constitution* (2006). These unpublished papers are available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/schedule.html>.

¹⁸⁰ *cf.*, Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1510 (2001) (arguing that because most patents are not of tremendous value, reform should be ex post rather than ex ante) (“The strong implication of these numbers is that society ought to resign itself to the fact that bad patents will issue, and attempt to deal with the problem ex post, when the patent is asserted in litigation. This result is admittedly counterintuitive. It depends crucially on the fact that very few patents are ever the subject of litigation, or even licensing. Because of this, money spent improving the PTO examination procedures will largely be wasted on examining the ninety-five percent of patents that will either never be used, or will be used in circumstances that don’t crucially rely on the determination of validity”).

¹⁸¹ See, e.g., Matthew Sag and Kurt Rohde, *A Differential Impact Analysis of Patent Reform*, Section B.1, p. 11ff (draft dated Aug 12, 2006) (focusing on examination related reforms and discussing both this reform proposal and other patent office initiatives such as limiting the applicant’s right to file continuations, streamlining examination by requiring applicants to designate representative claims, changing the rules relating to prior art search by applicants and their Information Disclosure Statements and offering an avenue for “accelerated review”), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/sag.doc>. The Patent Office has catalogued its proposed rule changes online at: Proposed Rule Changes to Focus the Patent Office in the 21st Century, available at <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html> (last visited Aug. 17, 2006).

This not only precipitates a rethinking of administrative reform, generally, it demonstrates that it is possible to improve decision making by enhancing the informational inputs into the process. Even were we to change the legislative standards by which patent determinations are made, without adequate information to enable a decision about what is novel and non-obvious, reform is not possible. Agencies depend on good information to do their work – whether it is determining patents or air quality – and they lack the institutional mechanisms and the institutional culture to benefit from outside expertise.

Focusing on the Patent Office qua agency not only shifts the discourse of reform to administrative practices, it makes the case for empirical and data-driven reform.¹⁸² The legal profession often prefers “anecdotes to tables”¹⁸³ and, with notable exceptions, there is a lack of empirical scholarship to support legislative change.¹⁸⁴ By designing and implementing a pilot to change

¹⁸² David A. Hyman, *An Outsider Perspective on Intellectual Property Discourse*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 276, 278 (F. Scott Kieff, ed.) (2003) (discussing evident lack of concern about the dearth of empirical evidence in legal scholarship); see also Jack Goldsmith and Adrian Vermeule, *Empirical Methodology and legal Scholarship*, 69 U. CHI. L. REV. 153 (2002); Richard Revesz, *A Defense of Empirical Legal Scholarship*, 69 U. CHI. L. REV. 169 (2002).

¹⁸³ David A. Hyman, *An Outsider Perspective on Intellectual Property Discourse*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 279 (F. Scott Kieff, ed.) (2003).

¹⁸⁴ For some of this recent empirical legal scholarship about intellectual property, see Barton Beebe, *An Empirical Study of the U.S. Copyright Fair Use Cases* (2006), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/Beebe.pdf>; William T. Gallagher, *Strategic Intellectual Property Litigation: An Empirical Study of Enforcement of Intellectual Property Claims*, available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/Gallagher.doc>; Paul Heald, *Copyright Ownership and Efficient Exploitation: An Empirical Study of American Works*, <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/Heald.doc>; Gregory Mandel, *Patently Non-Obvious, Patently Non-Obvious: How the Hindsight Bias Renders Patent Decisions Irrational* (2006); Lee Petherbridge and R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment for the Law of Obviousness* (2006), http://www.law.upenn.edu/polk/petherbridge_obviousness.pdf. See also Mark A.

workplace procedures, we can test the impact on the patent system. We can ascertain if such measures promote the progress of the useful arts. Rather than content ourselves with guesswork as to what legal reforms will address the patent crisis – wondering whether changing the standard of judicial review or reforming the obviousness standard will, in fact, improve patent quality -- open patent review will allow us to demonstrate reform in practice by means of defined metrics. We can inject more information into the process to inform examination and test the results. We can then lobby Congress for more thoroughgoing legislative change on the basis of concrete data as to what works and what does not work. Gathering data through empirical research shows how we might conduct public participation and develop new models and new technologies to solicit public, more specifically expert, input to improve regulatory decision making.

Lemley and Carl Shapiro, *Patent Holdup and Royalty Stacking* (July 12, 2006). Stanford Law and Economics Olin Working Paper No. 324 Available at SSRN: <http://ssrn.com/abstract=923468>.