

A PATENT SYSTEM FOR THE 21ST CENTURY

Statement of

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Good afternoon. I am Stephen Merrill, director of the program on Science, Technology, and Economic Policy (STEP) of the National Academies. I appreciate the invitation to participate in this hearing of the Antitrust Modernization Commission with the regard to study I directed for the Academies of the operation and effects on innovation of the U.S. patent system.

The Academies (of Sciences, Engineering, and Medicine) were chartered by Congress in 1863 to advise the government on matters of science and technology. Although most Academy studies are conducted in response to an agency's or a congressional request, the study I will describe was initiated by the board overseeing the STEP program because it recognized that the breakneck pace of technological change across many industries was creating stresses in the patent system that needed to be examined to ensure that it continues to be a stimulus to innovation and does not become an impediment to it.

Since 1980 a series of judicial, legislative, and administrative actions and diplomatic efforts have extended patenting to new technologies (biotechnology) and to technologies previously without or subject to other forms of intellectual property protection (software and business methods), encouraged the emergence of new players (universities), strengthened the position of patent holders vis-à-vis infringers domestically and internationally, relaxed other restraints on the use of patents (antitrust enforcement), and extended their reach upstream from commercial products to scientific research tools and materials.

As a result, patents are being more zealously sought, vigorously asserted, and aggressively enforced than ever before. Even though intellectual property protection plays very different roles in different sectors, there are many indications that firms in a variety of industries, as well as universities and public institutions, are attaching greater importance to patents and are willing to pay higher costs to acquire, exercise, and defend them. The workload of the U.S. Patent and Trademark Office has increased several-fold in the last few decades, to the point that it is issuing approximately 100 patents every working hour. Meanwhile, the costs of acquiring patents, promoting or securing licenses to patented technology, and prosecuting and defending against infringement allegations in the increasing number of patent suits are rising rapidly.

In spite of these changes and the obvious importance of patents to the economy, there had not been a broad-based study of the patent system's performance since the Depression. Accordingly, the Academies assembled a committee that included three corporate R&D managers, a university administrator, three patent holders, and experts in biotechnology, bioengineering, chemicals, telecommunications, microelectronics, and software, as well as economists, legal scholars, and practicing attorneys. The panel was chaired by Dr. Richard C. Levin, President of Yale University, and Dr. Mark Myers of the faculty of the University of Pennsylvania's Wharton School (and formerly Chief Technology Officer of Xerox Corporation). This diversity of experience and expertise distinguishes our panel from nearly all previous commissions on the subject, as does our study process. We held conferences and public hearings and we commissioned original empirical research on several topics. The committee's report, *A Patent System for the 21st Century*, released 18 months ago, provides a thoroughly researched, timely perspective on how well the system is working.

High rates of technological innovation, especially in the 1990s but continuing to this day, suggest that the patent system is working well and does not require fundamental changes. Nevertheless, the committee was able to identify five issues that should and can be addressed now.

First, maintaining consistent patent quality is important but difficult in fast-moving fields. Over the past decade, the quality of issued patents has come under frequent sharp attack, as it sometimes has in the past. One can always find patents that appear dubious and some that are even laughable – for example, the patent for cutting and styling hair using scissors or combs in both hands. Some errors are unavoidable in a system that issues more than 160,000 patents annually, and many of the seemingly most egregious errors will have no economic consequence because the patents will not be enforced. Still, some critics have suggested that the standards of patentability have been lowered by court decisions. Other observers fault the USPTO's performance in examining patent applications, variously attributing the alleged deterioration to inadequate time for examiners to do their work, lack of access to prior art information, perverse incentives to grant rather than reject patents, and inadequate examiners' qualifications.

Because the claim that quality has deteriorated in a broad and systematic way has not been empirically tested, conclusions must remain tentative. But there are several reasons to suspect that more issued patents are substandard, particularly in technologies newly subject to patenting. One reason to believe that quality has suffered, even before taking examiner qualifications and experience into account, is that in recent years the number of patent examiners has not kept pace with the increase in workload represented by the escalating number and growing complexity of applications. Second, patent approval rates are higher than in some other major nations' patent offices. Third, changes in the treatment of genomic and business method applications, introduced as a result of criticisms of the quality of patents being issued, reduced or at least slowed down the number of patent grants in those fields. And fourth, there does appear to have been some dilution of the application of the nonobviousness standard in biotechnology and some limitations on its proper application to business methods patent applications. Although quality appears to be more problematic in rapidly moving areas of technology newly subject to patenting and perhaps is raised over time, the cost of waiting for an evolutionary process to run its course may be too high when new technologies attract the level of investment exhibited by the Internet, biotechnology, and now nanotechnology.

What are the costs of uncertainty surrounding patent validity in areas of emerging technology? First, uncertainty may induce a considerable volume of costly litigation. Second, in the absence of litigation, the holders of dubious patents may be unjustly enriched, and the entry of competitive products and services that would enhance consumer welfare may be deterred. Third, uncertainty about what is patentable in an emerging technology may discourage investment in innovation and product development until the courts clarify the law, or inventors may choose to incur the cost of product development only to abandon the market years later when their technology is deemed to infringe. In sum, greater certainty about patent validity would benefit innovators, technological followers, and consumers alike.

Second, differences among national patent systems continue to result in avoidable costs and delays. In spite of progress in harmonizing the U.S., European, and Japanese patent examination systems, important differences in standards and procedures remain, ensuring search and examination redundancy that imposes high costs on users and hampers market integration. It

is estimated to cost as much \$750,000 to \$1 million to obtain comprehensive worldwide patent protection for an important invention, and that figure is increasing at a rate of 10 percent a year. Important differences include the following: Only the United States gives preference to the “first to invent” rather than the “first to file.” Only the United States requires that a patent application disclose the “best mode” of implementing an invention. U.S. law allows a grace period of one year, during which an applicant can disclose or commercialize an invention before filing for a patent, whereas Japan offers a more limited grace period and Europe provides none.

Third, some U.S. practices seem to be slowing the dissemination of information. In the United States there are many channels of scientific interaction and technical communication, and the patent system contributes more to the flow of information than does the alternative of maintaining technical advances as trade secrets. There are nonetheless features peculiar to the U.S. patent system that inhibit information dissemination. One is the exclusion of a nontrivial number of U.S. patent applications from publication after 18 months, an international norm since 1994. A second U.S. idiosyncrasy is the legal doctrine of willful infringement, which can require an infringer to pay triple damages if it can be demonstrated that the infringer was aware of the violated patent before the violation. Some observers believe that this deters an inventor from looking at the patents of possible competitors, because knowledge of the patent could later make the inventor subject to enhanced damages if there is an infringement case. This undermines one of the principal purposes of the patent system: to make others aware of innovations that could help stimulate further innovation.

Fourth, litigation costs are escalating rapidly and proceedings are protracted. Surveys conducted periodically by the American Intellectual Property Law Association indicate that litigation costs, millions of dollars for each party in a case where the stakes are substantial, are increasing at double digit rates. At the same time the number of lawsuits in District Courts is increasing

Fifth, access to patented technologies is important in research and in the development of cumulative technologies, where one advance builds on one or several previous advances. Faced with anecdotes and conjectures about restrictions on researchers, particularly in

biotechnology, we conducted a modest survey of diverse participants in the field to determine whether patent thickets are emerging or access to foundational discoveries is restricted. We found very few cases although some evidence of increased research costs and delays and much evidence that research scientists are largely unaware of whether they are using patented technology. During our study, the Court of Appeals for the Federal Circuit ruled that university researchers are not shielded by the common law research exception against infringement liability. This combination of circumstances – ignorance of intellectual property on the one hand and full legal liability on the other – represents an exposure that universities are not equipped to eliminate by the kinds of due diligence performed by companies and investors.

Toward a Better Patent System

The committee supports seven steps to ensure the vitality and improve the functioning of the patent system. Several of these are incorporated in bipartisan legislation (H.R. 2795) introduced in the House of Representatives this spring and the subject of several hearings. One recommendation is being dealt with in the appropriations process. Others remain to be addressed.

1) Preserve an open-ended, unitary, flexible patent system. The system should remain open to new technologies, and the features that allow somewhat different treatment of different technologies should be preserved without formalizing different standards; for example, in statutes that would be exceedingly difficult to draft appropriately and equally difficult to change if found to be inappropriate. Among the tailoring mechanisms that should be exploited is the USPTO's development of examination guidelines for new or newly patented technologies. In developing such guidelines, the office should seek advice from a wide variety of sources and maintain a public record of the submissions. The results should then be part of the record of any appeal to a court, so that they can inform judicial decisions.

This information could be of particular value to the Court of Appeals for the Federal Circuit, which is in most instances the final arbiter of patent law. To keep this court well

informed about relevant legal and economic scholarship, it should encourage the submission of amicus briefs and arrange for temporary exchanges of members with other courts. Appointments to the Federal Circuit should include people familiar with innovation from a variety of perspectives, including management, finance, and economic history, as well as nonpatent areas of law that bear on innovation.

2) *Reinvigorate the nonobviousness standard.* The requirement that to qualify for a patent an invention cannot be obvious to a person of ordinary skill in the art should be assiduously observed. In an area such as business methods, where the common general knowledge of practitioners is not fully described in published literature likely to be consulted by patent examiners, another method of determining the state of knowledge needs to be employed. Given that patent applications are examined *ex parte* between the applicant and the examiner, it would be difficult to bring in other expert opinion at that stage. Nevertheless, the open review procedure I describe next provides a means of obtaining expert participation if a patent is challenged.

Gene sequence patents present a particular problem because of a Federal Circuit ruling making it difficult to apply the obviousness test in this field. This is unwise in its own right and is also inconsistent with patent practice in other countries.

3) *Institute an “Open Review” procedure.* Congress should pass legislation creating a procedure for third parties to challenge patents after their issuance in a proceeding before administrative patent judges of the USPTO. The grounds for a challenge could be any of the statutory standards—novelty, utility, nonobviousness, disclosure, or enablement—or the case law proscription on patenting abstract ideas and natural phenomena. The time, cost, and other characteristics of this proceeding should make it an attractive alternative to litigation to resolve questions of patent validity. For example, federal district courts could more productively focus their attention on patent infringement issues if they were able to refer validity questions to an Open Review proceeding. The result should be much earlier, less expensive, and less protracted resolution of validity issues than we have with litigation and of a greater variety of validity issues than we have with the current re-examination procedure even if it were used.

4) *Strengthen USPTO resources.* To improve its performance, the USPTO needs additional resources to hire and train additional examiners and implement a robust electronic processing capability. Further, the USPTO should create a strong multidisciplinary analytical capability to assess management practices and proposed changes, provide an early warning of new technologies being proposed for patenting, and conduct reliable, consistent, reputable quality reviews that address office-wide as well as individual examiner performance. The current USPTO budget is not adequate to accomplish these objectives, let alone to finance an efficient Open Review system, although in the last two fiscal years congressional appropriations have approximated USPTO fee receipts, enabling additional hiring.

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

6) *Harmonize the U.S., European, and Japanese patent examination systems.* The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of applications granted or denied. The committee recommends that the United States should conform to practice elsewhere by adopting the first inventor to file system, abandoning the "best mode" requirement, and eliminating the current exception to the rule of publication of an application after 18 months. The committee also recommends that the U.S. government seek to have other jurisdictions adopt the practice of allowing a grace period between the first

disclosure of an invention (for example, in a scientific publication) and the filing of an application. These objectives should be pursued on a trilateral or even bilateral basis if multilateral negotiations do not progress.

7) Consider enacting a narrowly drawn exception from infringement liability for some research activities. Here we do not propose specific legislative language, but we do suggest some principles for Congress to consider in drafting a narrow research exception that would preserve the intent of the patent system and avoid some disruptions to fundamental research.

In making these recommendations, our committee was mindful that although the patent law is designed to be uniform across all applications, its practical effects vary across technologies, industries, and classes of inventors. There is a tendency in discourse on the patent system to identify problems and solutions to them from the perspective of one field, sector, or class. Although the committee did not attempt to deal with the specifics of every affected field, the diversity of the membership enabled us to consider each of the proposed changes from the perspective of very different sectors. Similarly, we examined very closely the claims made that one class of inventors—usually individuals and very small businesses—would be disadvantaged by some change in the patent system. Some of the committee’s recommendations—universal publication of applications, Open Review, and shifting to a first-inventor-to-file system—have in the past been opposed on those grounds. The committee reviewed very carefully, for example, how small entities currently fare in interference proceedings, examination, and re-examination. We also studied how European opposition proceedings impact small businesses. We concluded they enjoy little protection and in fact are often at a disadvantage in the procedures we propose to change. In short, we believe that our recommendations, on balance, would be as beneficial to small businesses and individual inventors as to the economy as a whole.

I appreciate the opportunity afforded by the Commission to testify on our conclusions and would be happy to answer any questions.