

A PATENT SYSTEM FOR THE 21ST CENTURY

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Executive Summary

Since its creation more than 200 years ago, the U.S. patent system has played an important role in stimulating technological innovation by providing legal protection to inventions of every description and by disseminating useful technical information about them. With the growing importance of technology to the nation's well-being, patents are playing an even more prominent role in the economy. There are many indications that firms of all sizes as well as universities and public institutions are ascribing greater value to patents and are willing to pay higher costs to acquire, exercise, and defend them.

Throughout its history the patent system has had to adapt to evolving conditions, and it continues to demonstrate flexibility and responsiveness today. Since 1980 a series of judicial, legislative, administrative, and diplomatic actions have extended patenting to new technology (biotechnology) and to technologies previously without or subject to other forms of intellectual property protection (software), encouraged the emergence of new players (universities and public research institutions), strengthened the position of patent holders vis-à-vis alleged infringers domestically and internationally, relaxed antitrust constraints on the use of patents, and extended the reach of patenting upstream from commercial products to scientific research tools, materials, and discoveries.

Continuing high rates of innovation suggest that the patent system is working well and does not require fundamental changes. We generally agree with that conclusion, but it is clear that both economic and legal changes are putting new strains on the system. Patents are being more actively sought and vigorously enforced. The sheer volume of applications to the U.S. Patent and Trademark Office—more than 300,000 a year—threatens to overwhelm the patent examination corps, degrading the quality of their work or creating a huge backlog of

pending cases, or both. The costs of acquiring patents, promoting or securing licenses to patented technology, and defending against infringement allegations in court are rising rapidly. The benefits of patents in stimulating innovation appear to be highly variable across technologies and industries, but there has been little systematic investigation of the differences. In some cases patenting appears to have departed from its traditional role, as firms build large portfolios to gain access to others' technologies and reduce their vulnerability to litigation.

In light of these strains, now is an opportune time to examine the system's performance and consider how it can continue to reinvent itself. In spite of its pervasive influence, patent policy for the last 50 years has been the preserve of practicing attorneys, judges, patent office administrators, and legally trained legislators. The National Academies believe that patent policy will benefit from the additional insights of economists, scientists, and engineers in different disciplines, inventors, business managers, and legal scholars, and they appointed our committee to reflect that diversity of expertise.

We in turn benefited from the insights and data of nine groups of scholars supported by the National Research Council's Board on Science, Technology, and Economic Policy (STEP) to conduct a series of policy-related empirical studies. These are collected in this report's companion volume, *Patents in the Knowledge-Based Economy*. This work is part of a growing body of economic and legal research since 1980. Still, it is quite limited, and the range of industries examined in any detail is quite narrow. We do not know whether the benefits of more and "stronger" patents extend very far beyond a few manufacturing industries, such as pharmaceuticals, chemicals, and medical devices. It is even less clear that patents induce additional research and development investment in the service industries and service functions of the manufacturing economy. One obvious conclusion of our work is that we need a much more detailed understanding of how the patent system affects innovation in various sectors. But even without additional study we can identify areas of strain, inefficiency, excessive cost on the one hand and inadequate resources on the other hand that need to be addressed now.

CRITERIA FOR EVALUATING THE PATENT SYSTEM

In circumstances that at this stage defy a comprehensive evaluation of the patent system's impact on innovation, we identify seven performance criteria that are widely thought to be important if not necessary conditions for innovation and that are in some degree measurable.

First Criterion: *The patent system should accommodate new technologies.* The U.S. patent system has excelled at adapting to change because it is a unitary system with few *a priori* exclusions. The initiative to extend patenting to new areas lies in the first instance with inventors and commercial developers rather

than legal authorities, and the system, while formally neutral, has features that allow for somewhat different treatment of different technologies.

The incorporation of emerging technologies is not always seamless and rapid; indeed, it often generates considerable controversy. Moreover, case law recognizes limits to patenting, confining patents to inventions that can be expressed as products or methods and excluding patents on abstract ideas and phenomena of nature. Some, although not all, members of the committee are concerned that recent fairly abstract patents cross this indistinct line and have unwisely limited public access to ideas and techniques that are important to basic scientific research.

Second Criterion: *The system should reward only those inventions that meet the statutory tests of novelty and utility, that would not at the time they were made be obvious to people skilled in the respective technologies, and that are adequately described.* Over the past decade the quality of issued patents has come under frequent sharp attack, as it sometimes has in the past. Some critics have suggested that the standards of patentability—especially the non-obviousness standard—have become too lax as a result of court decisions. Other observers fault the performance of the U.S. Patent and Trademark Office (USPTO) 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, or the qualifications of the corps of examiners.

The claim that quality has deteriorated in a broad and systematic way could be, but has not been, empirically tested. Therefore, conclusions must remain tentative. There are nevertheless 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, according to recent estimates taking into account patent continuations, overall patent approval rates appear to be higher than officially reported, and at least in the past few years have been higher than in the European and Japanese 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, has reduced or at least slowed down the number of patent grants in those fields. And fourth, there might have been some dilution of the application of the non-obviousness 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 is perhaps corrected 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 and biotechnology.

Third Criterion: *The patent system should serve its second function of disseminating technical information.* In the United States there are many channels of scientific interaction and technical communication, and the patent system contributes more 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 about 10 percent of U.S. patent applications from publication, although universal publication 18 months after filing has been 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 patent before the infringement. 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 triple damages if there were 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 Criterion: *Administrative and judicial decisions entailed in the patent system should be timely, and the costs associated with them should be reasonable and proportionate.* The elapsed time between the filing of a patent application and the patent examiner's first action on it and the time between filing and final disposition are lengthening, particularly in new technologies, although resolution takes longer in other countries than in the United States. By the same token, it takes an inordinately long time to resolve questions of patent validity in the courts, and the cost of the proceeding is escalating. The burden of costs and uncertainties, especially those entailed in challenging and defending patents, falls disproportionately on smaller, less experienced firms.

Fifth Criterion: *Access to patented technologies is important in research and in the development of cumulative technologies, where one advance builds upon one or several previous advances.* Faced with anecdotes and conjectures about restrictions on researchers, particularly in biotechnology, the committee initiated a modest, interview-based survey of diverse participants in the field to determine whether patent thickets were emerging or access to foundational discoveries was restricted. The results suggest that intellectual property in biotechnology is being managed relatively successfully. The associated costs are somewhat higher and research can sometimes be slowed, but it is rarely blocked altogether. There are, however, occasional cases of restricted access to foundational discoveries and to some diagnostic genetic tests. Universities have traditionally operated under an unwritten assumption that they would not be sued by patent holders for violating patents in the course of precommercial university research, but a ruling in 2002 by the U.S. Court of Appeals for the Federal Circuit made it clear that a university is not legally protected from patent infringement

liability. It remains to be seen whether this will change the behavior of patent holders toward university research, but universities are at greater risk.

Sixth Criterion: *Greater integration of or reciprocity among the three major patent systems would reduce public and private transaction costs, facilitating trade, investment, and innovation.* 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. These include differences with respect to assigning patent application priority, the requirement to disclose a technology's best implementation to qualify for a patent, the period, if any, allowed between publication of an invention and submission of a patent application, and whether all patent applications are published after 18 months.

Seventh Criterion: *There should be a level field, with intellectual property rights holders who are similarly situated (e.g., state and private institutions performing research) enjoying the same benefits while being subject to the same obligations.* In 1999 the Supreme Court struck down a law that denied a state's ability under the Eleventh Amendment to the Constitution to claim immunity against charges of infringing a patent or other intellectual property. Under the ruling a state institution such as a public university holding a patent could be in the position of asserting its patent rights against an infringer while successfully barring a patent holder from recovering damages for the university's infringement of a patent although the state institution might be enjoined from further infringement. A private university enjoys no protection from infringement suits. Although it is too soon to know what the effects of the Supreme Court decision will be, one possibility is that the disparity could influence decisions on where research is done.

RECOMMENDATIONS TO IMPROVE THE PATENT SYSTEM

The committee supports seven steps to ensure the vitality and improve the functioning of the patent system:

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, difficult to change if found to be antiquated or inappropriate, and at odds with U.S. international commitments. Among the tailoring mechanisms that should be fully exploited is the USPTO's development of examination guidelines for new or newly patented technologies, as has been done for computer programs, superconductivity, and genetic inventions. In

developing such guidelines the office should seek advice from a wide variety of sources and maintain a public record of the submissions, and the results should 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. Further, in order for the judges to keep themselves well informed about relevant legal and economic scholarship, the court 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 could have an effect on innovation.

2. *Reinvigorate the non-obviousness 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 opinions at that stage. Nevertheless, the Open Review procedure described below 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 whose practical effect was to make it difficult to make a case of obviousness against a biological macromolecule claimed by its structure. This is unwise in its own right and is also inconsistent with patent practice in other countries. The court should return to a standard that would not grant a patent for an innovation that any skilled colleague would also have tried with a “reasonable expectation of success.”

3. *Institute an Open Review procedure.* Congress should seriously consider 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, non-obviousness, disclosure, or enablement—or even 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 patent validity questions both for private disputants and for federal district courts. The courts could more productively focus their attention on patent infringement issues if they were able to refer validity questions to an Open Review proceeding.

4. Strengthen USPTO capabilities. To improve its performance the USPTO needs additional resources to hire and train additional examiners and fully 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 and individual examiner performance. The current USPTO budget is not adequate to accomplish these objectives, let alone to finance an efficient Open Review system.

5. Shield some research uses of patented inventions from liability for infringement. In light of the Federal Circuit's 2002 ruling that even non-commercial scientific research conducted in a university enjoys no protection from patent infringement liability and in view of the degree to which the academic research community especially has proceeded with their work in the belief that such an exception existed, there should be limited protection for some research uses of patented inventions. Congress should consider appropriate targeted legislation, but reaching agreement on how this should be done will take time. In the meantime the Office of Management and Budget and the federal government agencies sponsoring research should consider extending "authorization and consent" to those conducting federally supported research. This action would not limit the rights of the patent holder, but it would shift infringement liability to the government. It would have the additional benefit of putting federally sponsored research in state and private universities on the same legal footing without revising the recent Supreme Court's ruling shielding state universities from damage awards in patent infringement suits.

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

7. Reduce redundancies and inconsistencies among national patent systems.

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

In making these recommendations the committee is mindful that although the patent law is general, its 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 our membership enabled it to consider each of the proposed changes from the perspective of very different sectors. Similarly, in our deliberations we examined closely the claims made to us that one class of American inventors—individuals and very small businesses—would be disadvantaged by certain changes in the patent system. Some of our recommendations—universal publication of applications, Open Review, and shifting to a first-inventor-to-file system—have in the past been vigorously opposed on those grounds. We conclude that the evidence for such claims is wanting and believe that our recommendations, on balance, would be as beneficial to small entities as to the economy at large.