

and economic history, as well as nonpatent areas of law that could have an effect on innovation.

7) Shield some research uses of patented inventions from liability for infringement. It is unlikely that a reasonable common law research exemption will emerge from judicial decisions in current litigation. Congress should consider appropriate targeted legislation, but reaching agreement on how this should be formulated 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 under grants as is routinely done with contractors. This action would not ignore the rights of patent holders, but it would shift infringement liability to the government.

In making these recommendations, the committee examined closely the possibility that changes in the patent system to make it more efficient and less costly and to improve its output could nevertheless disadvantage individual inventors and small businesses, some of whom have in the past opposed measures such as Open Review, universal publication of applications, and the first-inventor-to-file basis of patent priority. The panel concluded that the evidence for such fears is lacking and that their recommendations would be as beneficial for small entities as for the economy as a whole.

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A PATENT SYSTEM FOR THE 21ST CENTURY

SUMMARY OF A STEP BOARD REPORT

Helping the Law and Institution Keep Pace with Technology

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The U.S. patent system is in an accelerating race with human invention and investments in innovation. Progress continues even in well-established technologies, and new technologies are emerging with greater frequency and attracting capital sooner. In many respects the patent system has responded with surprising speed and admirable flexibility, but the strain of continual change is exposing weaknesses. Meanwhile, too little effort has been made to understand how well patents are serving their dual purpose of providing incentives to innovate and disclosing technology that might otherwise be kept secret. In the end, the key question is what changes are needed to ensure that the system is an engine of progress, not an impediment to it.

WHAT'S CHANGED

Since 1980 a series of judicial, legislative, and administrative actions 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 growth 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 acquired, vigorously asserted, and aggressively enforced in court. The U.S. Patent and Trademark Office (USPTO) now receives 300,000 applications a year and issues 180,000 new patents. That represents 100 new patents every working hour, a burden not only on the agency but also potentially on commerce. 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 the costs of acquiring, exercising, enforcing and defending them; but those costs are rising rapidly.

Curious about the impact of these changes in the patent system on economic performance and concerned about the scarcity of evidence one way or the other, the National Research Council

assembled a study committee to evaluate it. The committee included a rich mix of legal expertise—a former federal judge, two patent attorneys in private practice, a corporate attorney, a former patent commissioner, and two legal scholars—as well as economists, scientists, engineers, inventors, university administrators, and corporate technology and intellectual property managers (see back page). Patent policy has not been reviewed by a group with equivalent diversity and depth of expertise in more than 50 years.

The committee held three formal conferences, conducted a series of roundtables and heard from interested parties from all sectors. Moreover, dissatisfied with the limited research literature on

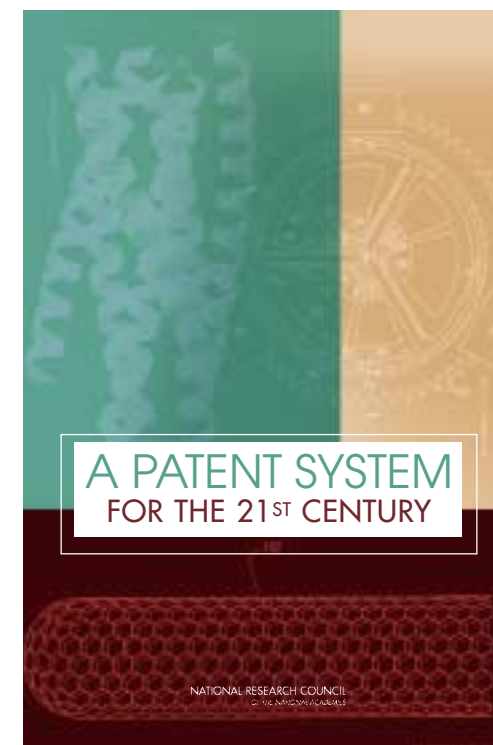
contemporary patenting, the committee supported new data collection on and analysis of patent quality, licensing, and litigation, focusing on information technology and biotechnology. The committee's report, **A Patent System for the 21st Century**, contains its findings and recommendations for strengthening the patent system. The research studies are collected in a companion volume, **Patents in the Knowledge-Based Economy**. The conference proceedings are available on a CD-ROM, **Patents in the 21st Century**.

SOURCES OF STRESS

The committee's first task was to identify areas where the patent system is under stress and where it is falling short. The following short list highlights what in the committee's view are the most pressing concerns.

Maintaining consistent patent quality is 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. Patent quality is important because patents on non-novel, use-less, or obvious inventions may confer market power without consumer benefit, encourage more infringement disputes, and create enough uncertainty to deter investment in research and development of economically important technologies. Some observers have suggested that the standards of patentability—especially the nonobviousness standard—have become too lax as a result of court decisions. Other observers fault the USPTO's performance in examining patent applications, variously attributing the alleged



deterioration to insufficient time for examiners to do their work, lack of access to prior art information, or the inadequate qualifications of the examiners themselves.

Because the claim that quality has deteriorated in a broad and systematic way has not been empirically tested, 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, patent approval rates are higher than officially reported and 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 method 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.

Costs are rising and decisions are taking longer, but there are reasons to doubt that they are as a result any better. The cost to a company of prosecuting a U.S. patent application ranges from \$10,000 to \$30,000 or more and of contesting or defending a patent in an infringement suit anywhere from \$500,000 to \$4 million. But it is the double-digit annual rate of increase in these figures that is most troublesome. The length of patent pendency and duration of litigation, although in some respects comparing favorably to those in Europe and Japan, are also increasing. The delays and costs entailed in resolving questions of patentability, the validity of issue patents, and infringement compound the uncertainty surrounding innovation, especially for smaller, less experienced firms.

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. These

include differences with respect to assigning patent application priority, the requirement to disclose a technology's best implementation to quality for a patent, and the period if any allowed between publication of an invention and submission of a patent application.

Some features of the patent system unnecessarily retard the dissemination of 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 a significant 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 inventors from looking at the patents of possible competitors, because knowledge of the patent could later make the inventor subject to triple 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.

Access to patented technologies is important in research and the development of cumulative technologies, where one advance builds upon one or several previous advances. The proliferation of upstream patents on scientific discoveries, especially in biomedical

science, has raised concerns about impediments to research in the form of access restrictions on key research tools or simply the difficulty of acquiring rights to use a variety of patented technologies from diverse parties. The results of a small survey commissioned by the committee suggest that intellectual property in biotechnology is being managed relatively successfully, but there are cases of restricted access to foundational discoveries and to some genetic diagnostic tests. Moreover, university scientists have traditionally operated under an assumption that they would not be sued for infringing a patent in the course of non-commercial research, but a 2002 ruling of the U.S. Court of Appeals for the Federal Circuit made it clear that a university or other nonprofit institution is not legally protected from patent infringement liability.

RECOMMENDED ACTIONS

1) 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 prescription 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. 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.

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 described above provides a means of obtaining expert participation if a patent is challenged soon after it is issued.

Gene sequence patents present a particular problem because of a Federal Circuit ruling that makes it difficult to turn down a patent application on the grounds of obviousness. This is unwise in its own right and inconsistent with practice in other countries. The court should return to a standard that would deny a patent for on a result that any investigator of ordinary skill could also have tried with a "reasonable expectation of success."

3) Strengthen USPTO capabilities.

To improve its performance, the USPTO needs sufficient 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.

4) 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 at 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 or otherwise misleading the USPTO. Investigating these questions requires time-consuming, expensive, and ultimately subjective pretrial discovery. The committee believes that significantly modifying or eliminating these rules would increase predictability of patent dispute outcomes and reduce the cost of arriving at them without substantially affecting the principles that these aspects of the enforcement system were meant to promote.

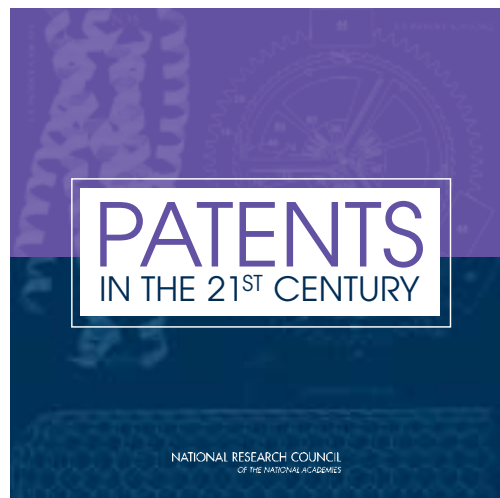
5) Harmonize the U.S., European, and Japanese patent examination systems.

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 results. Differences that need reconciling include application priority ("first-to-invent" vs. "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 be pursued on a trilateral or even bilateral basis if multilateral negotiations are not progressing.

6) 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 rules for different technologies, 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, 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. To keep themselves well informed about relevant legal and economic scholarship, Federal Circuit judges should encourage the submission of amicus briefs and arrange for temporary exchanges of members with other courts. Appointments to the appeals court should include people familiar with innovation from a variety of perspectives, including management, finance,



Patents in the 21st Century contains transcripts and presentations from three conferences held over the course of the project:

- **Intellectual Property Rights: How Far Should They Be Extended?** (February 2000)
- **Academic IP: Effects of University Patenting and Licensing On Commercialization and Research** (April 2001)
- **The Operation of the Patent System: Insights from New Research** (October 2001)



Patents in the Knowledge-Based Economy is a collection of 11 papers based on empirical research supported by the Board on Science, Technology and Economic Policy. Topics include patent quality, patent litigation, and patents in software and biotechnology.