REFORMING THE PATENT SYSTEM: TWO PROPOSALS

By Kurt M. Saunders

I. Introduction

Reform of the U.S. patent system has been the focus of two reports recently issued by the Federal Trade Commission (FTC) and the National Academies of Science (NAS). Each report was the result of a series of public hearings at which a number of business executives, economists, judges, scholars, and lawyers voiced serious and wide-ranging concerns about the effects of the patent system on economic development, competition, and technology innovation. The reports that emerged contained a number of proposals for legislative action and procedural reform. This article provides a background as to these reports and summarizes the proposals and recommendations contained in them.

A. Background to the FTC Report

In February of 2002, the FTC and the U.S. Department of Justice convened public hearings that took place over 24 days and involved more than 300 panelists. The hearings yielded testimony and presentations from business representatives of large and small firms, the independent inventor community, leading patent and antitrust organizations and practitioners, and scholars in economics and patent and antitrust law. Business representatives were mostly from high-tech industries, including pharmaceuticals, biotechnology, computer hardware and software, and the Internet. In addition, the FTC received approximately one hundred written submissions. The FTC issued its report, entitled To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy: A Report by the Federal Trade Commission, on October 28, 2003. The aim of the report was to assess how best to promote innovation by finding the proper balance of competition and patent law and policy, and to make recommendations as to how to maintain this balance.

B. Background to the NAS Report

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1 For detailed information about the hearings and copies of the materials submitted, see http://www.ftc.gov/opp/intellect/index.htm.


The project was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academies of Sciences and Engineering, and the Institute of Medicine. The Board concluded that intellectual property policy should be an important part of its agenda and that it should focus initially on the operation of the patent system. It therefore created the Committee on Intellectual Property Rights in the Knowledge-Based Economy, composed of economists specializing in intellectual property and technological change, legal scholars, practitioners from corporations and private law practice, biomedical scientists, managers of research and business development in the information technology sector, a former federal judge, and a former commissioner of the U.S. Patent & Trademark Office (USPTO). The Committee was charged with considering how the resources devoted to patent application review, the standards of patenting, and the patents issued have changed and how these affect incentives to undertake and communicate research and to commercialize new technology. Throughout 2001-2002, the Committee conducted public forums, taking extensive testimony from invited speakers. In April of 2004, the Committee issued its report, entitled A Patent System for the 21st Century.

II. Standards for Patentability

The reports consider extensively four aspects of patentability with regard to their impact on innovation and competition.

A. Patentable Subject Matter

Section 101 of the Patent Act permits patents to be granted on any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” Beginning with the Diamond v. Chakrabarty decision in 1980, the scope of patentable subject matter has steadily expanded. This trend has been furthered by the creation of the Court of Appeals for the Federal Circuit. Together, the Federal Circuit and the USPTO have extended the eligible subject matter of patents to include software, business methods, gene sequences, surgical procedures, and methods of performing sports. These extensions have led critics to argue that the PTO has been unnecessarily profligate in issuing patents, many of which become barriers, rather than incentives, to innovation.

The FTC report recommends that the Federal Circuit carefully consider possible harm to competition – along with other possible benefits and costs – before

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4 The National Research Council is the principal operating arm of the National Academy of Sciences and the National Academy of Engineering. It is a private, nonprofit institution that provides science and technology advice pursuant to Congressional charter.


7 447 U.S. 303 (1980)(genetically engineered microorganism held to be patentable).

8 For a more detailed discussion of these, see JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 169-94 (2003).
further extending the scope of patentable subject matter. The NAS report recommends preserving an “open-ended” patent system in which the Federal Circuit and USPTO treat different technologies differently, but “without formalizing different standards.”

B. Nonobviousness

A patent may be granted only for inventions that are nonobvious to those of ordinary skill in the relevant art.9 Many recent commentators have criticized the USPTO and the Federal Circuit for granting patents for inventions that are obvious.10 Both reports identified the standards applied by the Federal Circuit as the main reason for this concern.

The Federal Circuit regards an invention’s commercial success as presenting strong evidence that an invention is nonobvious. The marketplace is presumed to have provided others with the incentive to commercialize the invention. Therefore, if a commercially successful invention were truly obvious, then someone else would have commercialized it prior to the patentee.11 If a patented invention is a commercially successful product, the Federal Circuit may presume that the invention is nonobvious.12 Though the NAS report does not discuss use of the commercial success factor for nonobviousness, the FTC report suggests evaluation of commercial success on a “case-by-case basis as to whether commercial success is a valid indicator that the claimed invention is not obvious,” and by “placing the burden on the patent holder to prove the claimed invention caused the commercial success.”

In addition, a rejection of a patent application or challenge to the validity of a patent may be based on the position that two or more prior art references in combination render the invention obvious.13 As to inventions that are combinations of previously known elements, the Supreme Court has ruled that they are not patentable unless it has been demonstrated that the combination produced a new or unexpected result.14 The Federal Circuit, however, requires the patent examiner to also show specific documentary evidence that suggests a reason to combine previously known features found in different sources.15 Known as the “suggestion test,” the patent examiner is prohibited from relying on “common knowledge and common sense” without “any specific hint or

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11 See In re Baxter Travenol Labs, 952 F.2d 388 (Fed. Cir. 1991).
12 A challenger can rebut this presumption with evidence that the commercial success was due to factors other than the invention itself (e.g., advertising or marketing efforts). See id.
13 See In Re Lee, 277 F.3d 1338 (Fed. Cir. 2002); McGinley v. Franklin Sports, Inc., 262 F.3d 1339 (Fed. Cir. 2001).
15 See McGinley v. Franklin Sports, Inc., 262 F.3d 1339 (Fed. Cir. 2001).
suggestion in a particular reference to support the combination.”¹⁶ Such evidence is often difficult to uncover, particularly if the solution is obvious, since there is little incentive to document the solution of a problem that is obvious to solve.

The report by the FTC recommends that the courts should “assume an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art.” The NAS discusses this issue within the framework of business method patents, recognizing that much common knowledge about business methods is not published. The NAS does not recommend any changes in the “suggestion test,” but the report recommends that the nonobviousness standard should be “assiduously observed” and advocates a post-grant procedure to remedy deficiencies in the published literature regarding business methods.

C. Evidentiary Standards

When the USPTO decides whether to confer a patent, it does so based on the “preponderance of the evidence” standard; however, the Federal Circuit employs the higher and more difficult “clear and convincing evidence” standard, a higher standard of proof. The FTC report recommends that Congress enact legislation specifying that challenges to patent validity be determined based on a preponderance of the evidence standard. The NAS report contains no recommendations regarding the standard to be applied to challenges to patent validity.

D. Gene Sequence Patents

The Federal Circuit has set a low standard of nonobviousness for patenting gene sequences. Even though the patenting of genes as they exist in the human body would be considered products of nature and thus outside the scope of patentable subject matter, it is now quite routine for biotechnologists to determine a gene sequence based on knowledge of the protein that the gene generates. The Federal Circuit has considered a gene sequence nonobvious even when the resulting protein is already known.¹⁷ According to the NAS, this effectively removes nonobviousness as a consideration for gene patents. While the FTC did not make recommendations regarding the patenting of gene sequences, the NAS suggests that genetic sequences should be considered obvious if the proteins created by the genes are known.

III. USPTO Operations

The USPTO is responsible for implementing the patentability standards when reviewing patent applications. Many of the policy recommendations concerned its operation.

¹⁶ See In re Lee, 277 F.3d 1338 (Fed. Cir. 2001) (rejecting reference to the desirability to combine as common knowledge among those skilled in the art).
¹⁷ See In re Duel, 51 F.2d 1552 (Fed. Cir. 1995).
A. Post-Grant Opposition Proceeding

The patent examiner must notify the applicant of his or her response to the application and has the burden of proof for demonstrating that invention is unpatentable.\textsuperscript{18} In practice, patent examiners have limited access to prior art other than previously-issued patents. Furthermore, the applicant’s competitors may have better information about the field of technology than that available to the patent examiner, and they may be more interested in ensuring that an otherwise invalid patent is not granted.

Accordingly, both reports propose that the U.S. establish an administrative proceeding after a patent has been granted so that other parties can bring invalidating evidence to the attention of the USPTO. Such a proceeding would be less expensive and faster than a full trial and more effective than the current re-examination procedure. Moreover, such a procedure is already applied successfully in the E.U. Both the FTC and the NAS reports call for the creation of a new administrative procedure providing for post-grant review of and opposition to patents.

B. Continuing Applications

The use of “continuations,” including “divisionals” and “continuations in part,” has been an ongoing source of controversy as to USPTO examination procedure. Once a patent application has been initially rejected, or sometimes before it is rejected, the applicant can file a “continuing” application that preserves the priority date of the original application.\textsuperscript{19} This has the effect of allowing the applicant to repeat arguments or present new arguments or evidence to the patent examiner, or to modify patent claims, either to correct drafting errors or for other reasons, without the necessity of an appeal.\textsuperscript{20} Moreover, patent claims can be amended even after applications are published.

The net effect is that applicants often can have continuing applications pending for years, while sometimes broadening the claims, without public disclosure. Both the NAS and FTC reports recommend mandatory publication of patent applications 18 months after filing. Additionally, the FTC report recommends a limited prior user right: if a defendant is found to infringe only because a patent claim was amended and before the amended claim is published, the defendant should be able to avoid liability.

C. USPTO Funding

Both reports recommend increased funding for the USPTO for work force and technology improvements so that it can improve the quality of issued patents.

D. Other Recommendations

\begin{itemize}
  \item \textsuperscript{18} See 35 U.S.C. § 132 (2002).
  \item \textsuperscript{19} See 35 U.S.C. § 120 (2002); 37 C.F.R. § 1.60 (2000).
  \item \textsuperscript{20} See Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551 (Fed. Cir. 1994).
\end{itemize}
The NAS report also recommends that the USPTO implement a strong electronic processing capability and a thorough “multidisciplinary analytical” capability to assess and implement management practices, new technologies, patent quality, and to evaluate individual examiner performance. The FTC report more broadly advocates that “economic learning and competition policy considerations should be integrated into patent law decisions.”

IV. Infringement and Other Issues

The effectiveness of patent protection depends not only on the remedies available for infringement, but also the nature of the defenses available to avoid liability.

A. Willful Infringement

If a defendant knowingly infringes a patent, he or she may be subject to damages up to three times the compensatory award. Some who testified at the hearings stated that they avoid reading patents in order to preclude this penalty. The NAS report proposes that this provision of the Patent Act be significantly amended or eliminated. The FTC report recommends that a patentee claiming willful infringement be allowed to seek treble damages only when he or she has provided written notice sufficient to allow an alleged infringer to challenge the validity of the patent, or when the alleged infringer has deliberately copied the invention, with knowledge that it is patented.

B. Good Faith and Disclosure by Patent Applicants

To deter bad faith and improper conduct before the USPTO, if a court finds that a patent applicant withheld important information, the court can choose to invalidate or not enforce a patent. Such a result will ensue if an applicant engages in inequitable conduct by intentionally failing to disclose prior art that might invalidate the patent, or if the patent application knowingly fails to inform the public of the best mode to implement the invention. The NAS report contends that these rules add to the expense of patent trials because they both require a complicated determination of the patent applicant’s state of mind at the time of the application. The NAS report recommends that these rules be greatly modified or eliminated. The FTC report, on the other hand, made no recommendations regarding these rules.

C. Experimental Use

The courts have long recognized non-licensed use of a patented invention for experimental or research purposes as a defense to patent infringement. Academic institutions have relied on this defense to conclude that researchers

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23 See 35 U.S.C. § 112, ¶1; see also Chemcast Corp. v. Arco Indus., 913 F.2d 923 (Fed. Cir. 1990).
using a patented invention for experimental purposes were immune from liability for infringement. However, the recent Federal Circuit decision in *Madey v. Duke University* has significantly narrowed this defense. The court held that a university can be held liable for patent infringement even if it is using the patented intellectual property rights of others only for non-commercial internal research or educational purposes. The FTC report raises concerns about the potential chilling effect of the *Madey* decision on academic research. The NAS report recommends “appropriate targeted legislation” to provide “limited protection for some research uses of patented inventions” and urges that the U.S. government assume liability for patent infringement by federally-funded researchers.

**D. Other Matters**

The U.S. is the only country whose patent system does not give priority to the first inventor to publicly disclose an invention and seek patent protection. The NAS report recommends that the U.S., E.U., and Japan harmonize their patent procedures and standards as to the rules for determining priority. Proposed changes in U.S. patent rules include changing from a first-to-invent priority system to a first-to-file system and mandatory publication of all patent applications after 18 months.

Likewise, the FTC report also recommends that economic policy considerations should be integrated into patent law decisions, and that the USPTO continue to acknowledge that it balance both the public interest with the applicant’s interest in issuing a patent. The report also supports the USPTO’s proposal to expand its “second pair of eyes” review and advises that the program cover semiconductors, software, and biotechnology.

Finally, the FTC report proposes to increase cooperation between the USPTO and FTC by: establishing a liaison panel between the FTC, Department of Justice Antitrust Division, and the USPTO; creating an Office of Competition Advocacy within the USPTO; and requesting that Congress expand the Patent Public Advisory Committee to include competition law experts and economists. The FTC also intends to continue filing amicus briefs in cases that involve antitrust and patent law issues, and to ask the USPTO to reexamine questionable patents when such action is justified.

**V. Conclusion**

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25 64 U.S.P.Q.2d 1737 (Fed. Cir. 2002).

26 The court held:

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

*Id.* at 1742.
Whether anything comes of the recommendations of the FTC and the NAS remains to be seen. Some of the recommendations can be implemented internally by the USPTO, while others will require Congressional action. It is likely that many of the recommendations will elicit the attention of industry and inventors, while some of the bolder, more controversial proposals will draw strong opposition. Whatever the result, we should brace ourselves for another round in the debate between property rights and the public domain.