The Courts and Innovation

PAULINE NEWMAN, *Judge, U.S. Court of Appeals for the Federal Circuit, U.S.A.*

ABSTRACT

Established and enforceable rules of law can provide just and expeditious resolution of the disputes that are inevitable in vigorous commerce. But in the rapidly evolving subject matter of biotechnology, this science can bring to court issues for which there is no precedent and about which there is no consensus. The rule of law, however, is vibrant, adapting to the evolving contexts of science and technology. In today's era of rapid technological change, jurisprudence provides the stability of the law, while reflecting the social implications of the science. But the scientific and technologic issues of today, such as arise in IP disputes, must also be correctly decided to promote a uniform and predictable application of the law that promotes commercial stability adequate to support industrial innovation and the national interest.

1. INTRODUCTION

The role of courts in technology development, protection, transfer, and commercialization, in biotechnology as in all fields, is a combination of the traditional role of courts in dispute resolution and the common-law role of courts in the evolution of law. In a national and world economy that is increasingly technology based and yet governed by jurisprudence reflecting cultural norms, new fields of science and technology propel the courts into proceedings and decisions of economic and societal impact.

With respect to commerce and trade, legal systems have been described as having three missions. The first is to establish the rights and rules of property ownership, including intellectual property (IP). The second is to protect property rights from illegal disposition by guarding against civil wrongs and crimes. The third is to provide and enforce the rules of exchanges and transfers of property: the laws of contracts and sales and competition. In addition, legal systems establish rules for entering and leaving commercial activity, such as corporate law and bankruptcy law, and rules that promote competition and innovation, such as antitrust and IP law. In the development, management, and transfer of technology, effective legal systems provide stability and predictability of national and international force. This concept is globally applicable: strengthening the rule of law has broad-ranging implications for every country and organization. In regard to IP laws, which partake of so many interrelated policies, understanding how the courts balance conflicting policies can provide useful guidance to business, technology managers, and scientists.

Litigation in the fields of today's biological advances takes us to the edge, not only of science, but also of conflicting policies—often at the limit of judicial experience. Justice Holmes said, "The life of the law has not been logic: it has been experience." Human experience absorbed science and technology into the common law and its basic concepts of property, human responsibility, and fairness. But litigation of disputes concerning

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science and technology is bringing new challenges to the search for justice through truth—the foundation of judicial systems.

Judges do not create national policy or industrial policy; such policy finds its origins in the cultures of nations, and its sustenance in the laws of nations. Yet policy comprehension is essential to judicial decisions. When technology and biology are involved, then the jurisprudential overview (as well as the decision of individual cases) can affect the nation's economy and the public interest. It will additionally have an even broader global impact. This *Handbook* arises from the premise that developing the products of science and technology is of profound public benefit, a benefit that requires both scientific and industrial participation. This is a many-faceted concept, yet today we exist in an era of such pervasive scientific and technological advance that the development of these benefits, and their movement into commerce and among nations, warrant our most concerned efforts.

2. THE COURTS AND TECHNOLOGIC ADVANCE

The courts implement the rules by which society chooses to be governed. A reliable mechanism of dispute resolution eases the path to sustainable technologic advance, economic growth, and ensuing public benefit. Established and enforceable rules of law can provide just and expeditious resolution of the disputes that are inevitable in vigorous commerce. In the rapidly evolving subject matter of biotechnology, this science can bring to court issues for which there is no precedent and about which there is no consensus. In such areas, legal issues arising from developments in science and technology often reach the courts for primary resolution, and the decision can affect both economic and technologic advance.

An example is seen in the U.S. Supreme Court's decision in the *Chakrabarty* case in 1980,[1] when despite predictions of the dire consequences of authorizing patents on *life forms*, the Court opened the nation's economy to industrial biotechnology, enabling commercialization of this nascent field, to the human benefit that is today bearing fruit. The growth of the biotech industry is a testament to judicial vision, for the U.S. Patent Office had refused to patent Dr. Chakrabarty's modified bacterium that was designed to digest oil spills. It was the Court of Customs and Patent Appeals and the Supreme Court that held otherwise.

Another example is seen in the U.S. Court of Appeals for the Federal Circuit, created for the purpose of revitalizing technologic innovation in a faltering economy. The industrial and scientific communities had recognized that national policy, as implemented in the courts, was inadequately supporting industrial innovation, a failure attributed to an inadequate understanding of the relationships among scientific research, technologic advance, and commercial investment. The adverse effects included a negative balance of trade, retrenchments in industrial R&D, mass layoffs of scientists and engineers, sparse capital formation, stagnation in productivity, and loss of international competitiveness.

Judicial misunderstanding of the system of patents and its purposes and processes was a primary problem. As a result, patents were not viewed as reliable support for commercial investment, for they could be litigated in circuit after circuit until they fell. And the Justice Department's "nine no-no's" of patent licensing were a further disincentive to technology transfer. During the economic recession of the late 1970s, the retrenchment of investment in new technologies was so severe that dramatic remedies were accepted—including the first major change in the federal judicial structure in a hundred years.[2]

Thus the federal judicial system was restructured to provide a national appellate court that would receive all patent appeals throughout the nation, whether from the district courts, the International Trade Commission, or the Patent Office.[3] The hope was that a single appellate court would better understand, and correct, the policy misperceptions that had led to a judge-made reduction of the patent incentive for investment in technologic advance. The goal was a uniform and predictable application of the law that would promote commercial stability adequate to support industrial innovation. The change was not without vigorous controversy, but it was implemented

with the congressional leadership of Wisconsin Representative Robert W. Kastenmeier and senators Robert Dole and Patrick Leahy. It was an extraordinary and creative action to change the nation's court system as an incentive to technologic advance. And the effect of this juridical change was dramatic, as entrepreneurial business as well as established industry returned to developing new and improved technological products.

The change in industrial activity based on a strengthened patent incentive surpassed the most optimistic expectations. One rarely sees so direct a relationship between judicial structure and commercial vigor.

3. THE EVOLVING PATENT JURISPRUDENCE

The legal framework of technology movement into public availability through market forces partakes primarily of the law governing all commerce. As for all laws, the overarching consideration is the national interest. Patent law is designed to serve as an incentive to promote technologic research and industrial commercialization, not only to bring to the public the benefits and conveniences of new technologies, but also to achieve a vigorous combination of industrial products and employment and trade. These societal and economic policies undergird the laws of intellectual property.

Starting about two decades ago, the U.S. Court of Appeals for the Federal Circuit methodically undertook to restore the patent law to the legal mainstream. In decisions applying across all areas of technology, the court implemented the patent statute and revived dormant legal principles. Some examples are the rulings that

- summary judgment is as available in patent cases as in any other
- consent judgments and settlement agreements in patent cases are not contrary to public policy
- an assignor can be estopped from challenging the validity of an assigned patent, as others are estopped who transfer property for value
- infringement is a wrong and subject to remedy like other torts
- the measure of damages is to make the injured party whole, as for other torts
- patents are presumed valid, as the statute requires
- proof of inequitable conduct in patent prosecution requires both materiality and deceptive intent
- preliminary injunctions in patent cases are decided on the same criteria as in other fields (as recently clarified by the Supreme Court[4])

The court, in its first years, developed objective standards for determination of obviousness (this topic is at present under review by the Supreme Court), applied the same law to the Patent Office and to the courts, eliminated appellate forum shopping, and generally restored the effectiveness of the patent system as support for industrial innovation. Much media attention was given to the "new strength" of patents.

Subsequent decisions of the Federal Circuit and the Supreme Court were geared toward refining the law and adding precision, for many decisions depend more on the science and technology than on the letter of the law. To this end, the court adjusted the roles of judge and jury in interpreting patents. The *Markman*[5] case, assigning the interpretation of patent claims to the judge instead of the jury, has affected trial procedures as well as the content and interpretation of patents. This decision and its implementation are still not free of controversy. Another controversial decision, *Festo,*[6] reduced the patentee's access to unclaimed technological equivalents, generally limiting patentees to what they actually described. The main emphasis of these decisions is the enhancement of predictability of patent scope, an emphasis that has led to requiring more technical description by the inventor and often more development of the inventive subject matter. The balance between a rigorous-notice function of patent claims and the cost of protecting the innovator against imitators who use the inventive concept but manage to skirt the claims warrants an objective evaluation of the benefits and obstacles presented by this direction of the law, as the interested communities seek the optimum policy and its legal implementation.

New issues of law are constantly arising, for developments in biological science and their application present factual situations that do not easily fit into precedent, such as questions of patentable subject matter, or the nature and conduct of scientific research. Such questions reach the courts when disputes arise; as, depending on the facts of the case, the courts try to implement the law in line with statute, precedent, and a judicial balance of practical economics, research incentive, and fairness. With each judicial decision, precedent adds its weight to one or another competing policy, for there are many facets to the legal and economic theory of intellectual property. For example, some theorists see patents primarily as an economic tool; some as founded on principles of natural right and fairness. Some are concerned lest the patent law impede the flow of ideas and knowledge; others suggest that without patents, fewer ideas and less knowledge would be generated, and even less used for public benefit. Much of the controversy concerning the role of patents arises, I believe, from vested interests that emphasize one or another of the purposes and uses of patent systems, as the courts apply a one-law-fits-all structure to service the public and national interests.

4. ADJUDICATING ISSUES OF SCIENCE AND TECHNOLOGY

Judicial interpretation and application of every aspect of IP law is challenged by the complexity of science and technology. In Thomas Jefferson's day, an educated person could understand every known technological aspect of life. Today we litigate questions whose scientific framework strains even persons within the corresponding discipline. These include the classical areas of technological applications of law, such as medical causation and product liability, as well as environmental issues and patent infringement; these questions also include new issues of constitutional and personal and commercial rights that flow from new scientific knowledge and its applications.

The scientific issues in litigation are rarely straightforward, and they tend to fall in incompletely explored areas and are often intermingled with policy concerns. The ongoing scientific advances in biology and genetics come to court in many guises: there are issues of criminal behavior, employment, insurance, and medical and product liability, as well as intellectual property. No matter how finely tuned a judge's judicial intuition, no matter how wise and benevolent, cases that turn on findings of science or technology cannot always be decided using the judge's traditional tools of reasoned analysis, an instinct for credibility, and worldly experience.

How then can the truths of science and technology be found in the courtroom? The just resolution of issues that turn on such findings presents a profound challenge to the administration of justice. Despite this concern, most judges prefer not to depart from the procedures of the adversary system—not as a matter of principle but of experience. Judges learn that not all scientific questions have clear answers; we have learned that scientific truth is often a matter of the honest but divergent viewpoints of scientist witnesses and that many of the questions of science and technology that come to court do not have a firm answer. Scientific facts are not like the traditional facts of lawsuits, based on the human components of recollection and credibility. In traditional judicial fact finding there are gradations of truth or falsity, questions of weight and value of evidence. What judges call "facts" are matters on which there is a difference of opinion, while scientific facts are supposed to be objective and absolute. The problem is that for issues in litigation the scientific answer is often unknown at the time of the lawsuit. By requiring the judge to decide questions that the scientists have not decided—and perhaps cannot decide—on the present state of knowledge, the side with the burden of proof simply is penalized.

Yet there is a natural partnership between jurisprudence and science, for both enhance our understanding of natural law. Both the law, and the science it deals with, progress along irregular pathways, via incremental steps in diverse directions, sometimes with false starts and often encountering dead ends, building on the past until the present presents a coherent and stable body of knowledge. Justice Felix Frankfurter called the decision-making process the "correlation of

imponderables," a term never more apt than in the evolving fields of biotechnology.

The rule of law is vibrant, adapting to the evolving contexts of science and technology. In today's era of rapid technological change, jurisprudence provides the stability of the law, while reflecting the social implications of the science. But the scientific and technologic issues of today, such as arise in IP disputes, must also be correctly decided.

For determining the reliability of scientific and technologic evidence, the Supreme Court has exhorted judges to apply the same standards as the scientific community. That is not easy, for although judges can readily understand the methodology of science, it is the science itself that is daunting. Habits of logical thinking, precision of reasoning, are common to science and law, each an elegant intellectual blend of theory and testing that leads the mind through complexity. Although as judges we do not test our theories in the laboratory, we do test them against the accumulated knowledge and wisdom of the past. This is the tradition and strength of the common law, as it continually adapts and is usefully and effectively applied to the new biology.

5. WHAT ABOUT THE FUTURE?

A major problem in judicial decision-making is how to achieve practical justice for the high-tech, science-based issues of today's disputes. The problem goes beyond the laws of intellectual property, for many issues that reach the courts (for example, in environmental law, communications technology, product liability, forensics and other criminal issues) turn on questions of science and technology of a complexity that did not exist even a few years ago. These issues require full access to the rule of law, with its protection of the public interest and private rights, its safeguards to litigants, its concern for legislative intent, its openness, its checks and balances. Its justice.

The rule of law contemplates a living law, adapting to changing contexts while benefiting from the experience of the past. Judges must understand the social and economic fabric of the statutes and precedent that we apply. It is essential to preserve a stable jurisprudence, lest we build uncertainty into areas whose strengths lie in their reliability. Yet new questions are constantly arising, or old questions in new contexts, such as the question of whether there is, or should be, a research exception to the use of another's patented invention. No one really worried about that question until science, particularly biological science, reached the stage where the boundary between basic and applied research was blurred or lost.

For the new biology, in general the law has lagged the science. Law usually lags social change. The evolution may be too slow for the enlarging issues of biology and genetics, as well as the developing issues of biodiversity and agri-biotechnology. As we ponder the legal and policy aspects of these new sciences (for example, with respect to advances in genetic science), constitutional principles arise. Is the preservation of human diversity—including the sick, or the ugly, or the moronic—a constitutional question? Justice Holmes is still criticized for ruling that "three generations of imbeciles is enough."[7] Would he be criticized for ordering remedy in the womb—or for denying such remedy? The cases in court often inspire thinking about the foundations of the law, as well as the historical and social and economic policies of the law.

Disputes arising in the biological sciences are likely to encounter the uncertainties of this jurisprudence, for the new biology raises new issues in the context of commerce and the interaction of public and private interests. I encourage you who are engaged in the creation and dissemination of these sciences to think about what the law should be, so that together we may seek the optimum legal framework for today's and tomorrow's scientific and technologic advances. ■

PAULINE NEWMAN, *Judge, U.S. Court of Appeals for the Federal Circuit, National Courts Building, 717 Madison Place NW, Washington, DC, 20439, U.S.A.* NewmanP@cafc.uscourts.gov.

1 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

2 The Bayh-Dole Act, discussed elsewhere in this *Handbook*, was also implemented at this time, as part of the larger purpose of revitalizing commercial development of the products of academic science.

See also, in this *Handbook*, chapter 3.3 by GD Graff and chapter 3.2 by R Nugent and J Keusch.

3 This patent-related jurisdiction was initially about 12% of the Federal Circuit's assignment, for the plan was to assure diversity and breadth of experience and responsibility. The number of patent-related cases has since increased, but they are still a minority of the court's assignment, which includes claims against the government, childhood vaccine injury cases, tax cases, Native American claims, veterans appeals, Fifth Amendment property takings, international trade and customs cases, and several other areas of national appellate jurisdiction.

4 *eBay v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

5 *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

6 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

7 *Buck v. Bell*, 274 US 200 (1927).