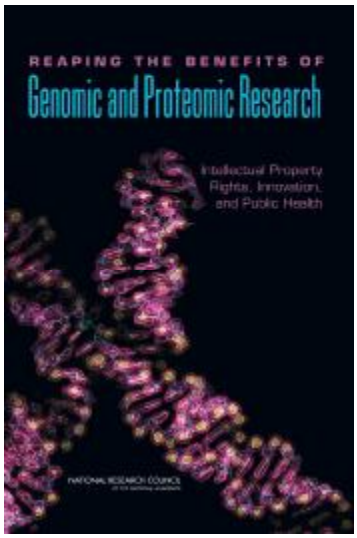
THE NATIONAL ACADEMIES
REPORT IN BRIEF



REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH

Intellectual Property Rights, Innovation, and Public Health (2006)

The molecular era in biology in the 1940s and 1950s and the development of recombinant DNA tools in the mid-1970s made it possible for scientists to isolate individual genes and determine their chemical composition, and ultimately to sequence entire genomes. The sequencing of the human genome with the Human Genome Project, nearly completed in 2003, has provided arguably the most powerful dataset in biomedical research. These milestones have explained how genes are assembled into genomes, answered questions regarding evolution, increased knowledge about genetics, and led to the development of new treatments for diseases.

The potential benefits of these discoveries require careful scrutiny when protecting intellectual property (IP) in the fields of genomics, the study of an organism's genome and the functions of genes, and proteomics, the large-scale study of protein structures and functions. Patents are sought by scientists in all sectors for research in these areas. The freedom of others to conduct research on a gene or protein and their ability to use them in healthcare could be constrained by the existence of a patent.

In recent years, the U.S. Patent and Trademark Office (USPTO) has been inundated with requests for patents on genes, gene fragments, proteins, and methods to study or produce them. Because thousands of genes or proteins can now be examined simultaneously, there is the possibility that a number of restrictions could impede scientific progress by blocking access to previous findings. In light of this changing environment, the National Institutes of Health (NIH) asked the National Research Council (NRC) to study the granting and licensing of IP rights on discoveries relating to genomics and proteomics, and the effects of these practices on research and innovation.

The patent landscape could become considerably more complex and burdensome over time. Several steps may be taken to anticipate and prevent problems for research in genomics and proteomics in the near future, as more knowledge is created, more patent applications are filed, and more restrictions are placed on access to information and resources. The nation's policy-makers, courts, and health and patent officials should take the steps outlined below to prevent the increasingly complex web of IP protections from getting in the way of potential breakthroughs in genomic and proteomic research.

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

National Academy of Sciences • National Academy of Engineering • Institute of Medicine • National Research Council

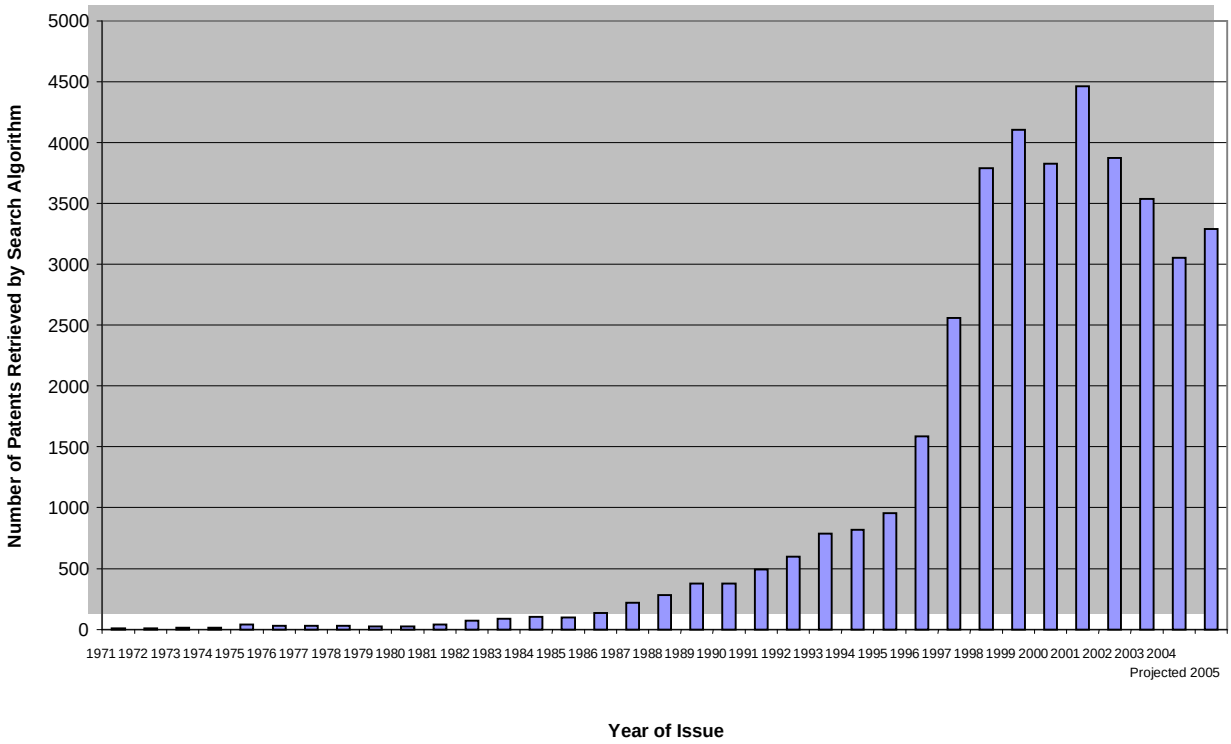


Figure 4-1 Number of DNA-based U.S. Patents (as of June 30, 2005) 2005 Projection is based on mid-year total. Source: Georgetown University Database

BEST PRACTICES

Many of the potential problems for genomics, proteomics, and IP can be avoided if scientists and institutions follow the best practices already outlined by NIH, NRC, and others to facilitate the free exchange of materials and data.

Foster Free Exchange of Data, Information, and Materials

NIH should continue to encourage the free exchange of material and data among its grantees and contractors. Additionally, NIH should require these individuals to comply with the agency's guidelines for obtaining and disseminating biomedical research resources and for licensing genomic inventions. Industries and nonprofit institutions should standardize and streamline their processes for exchanging biological material or data.

NIH also should adapt and extend the "Bermuda Rules," which were created in 1996 by scientists involved in the publicly funded Human Genome Project. The rules instruct genomics researchers to share their data in a free public database called GenBank. They should be extended to include protein-structure data that NIH-funded centers generate for large projects in genomics. Researchers in both the public and private sectors should make this information freely available in the Worldwide Protein Data Bank, a project overseen by a consortium of international research groups.

Foster Responsible Patenting and Licensing Strategies

NIH has issued two publications, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* and *Best Practices for the Licensing of Genomic Inventions* that provide guidance to NIH-funded institutions on balancing the need to protect IP rights with the need to broadly disseminate new discoveries and to maximize the public benefit whenever technologies owned or funded by the Public Heath Service are transferred to the commercial sector. NIH should require recipients of all research grants and awards, cooperative agreements, contracts, and intramural research studies to follow these

guidance documents. Other funding organizations (such as other federal agencies, nonprofit and for-profit sponsors) should adopt similar guidelines.

In addition, patent recipients should analyze whether further research, development, and private investment are needed to realize the usefulness of their research results and that proprietary or exclusive means of dissemination should only be pursued when there is a compelling need. Also, whenever possible, licenses should be limited to relatively narrow and specific commercial application rather than as blanket exclusive licenses for uses that cannot be anticipated at the moment.

ADAPTING THE PATENT SYSTEM TO GENOMICS AND PROTEOMICS

Some of this research has the potential to blur the boundaries between abstract ideas and applications. USPTO should create a formal mechanism, such as an advisory board of leading scholars in these fields, to inform examiners of new developments and research directions and to improve the understanding of complex and rapidly evolving technologies.

Nonobviousness

To qualify for a patent, an invention must be useful and represent a creative leap; it cannot be obvious to a person of ordinary skill in a given area. When applying the "nonobviousness" standard to genomic and proteomic inventions, USPTO and the courts should consider whether a scientist of ordinary skill would have been able to create a given invention with reasonable expectations of success at the time the invention was made.

Utility Standard

The Supreme Court established a standard in its 1966 decision in *Brenner v. Manson* requiring that a patent applicant show that an invention has “specific benefit in its current form.” However, this standard has not been applied in a consistent manner. Investigators and their institutions should avoid seeking patents for genes or proteins whose functions are unknown. These include proteins that are useful for research but do not have therapeutic or diagnostic functions.

FACILITATE RESEARCH ACCESS THROUGH LICENSING AND SHIELDING FROM LIABILITY FOR INFRINGEMENT

Experimental Use Exemption

A federal appellate court recently rejected the claim that the so-called "experimental use" legal defense shields academic research from patent infringement liability. In the future, academic and other nonprofit research institutions may feel compelled to protect themselves from liability by trying to regulate investigators' behavior. This may hinder research and fail to prevent legal problems because researchers are often unable to determine how existing patents apply to their work. It is also possible that patent holders, knowing that universities do not currently have legal protection from such liability, could increase demands for patent-licensing fees or dictate other terms that would burden the research enterprise. The situation could worsen over time as licensing restrictions imposed by patent holders increase. Congress should consider legislation that would allow scientists to conduct research on patented inventions in order to discover novel uses or improvements without fear of liability for patent infringement.

Patent Pooling

A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or third parties. Patent pooling is an approach that might address some issues of access to patented upstream technology and its possible applications to biomedical research and development. One issue that may be important in the health field is the willingness of academic scientists to have their inventions pooled if that would reduce their share of royalties provided by universities. Therefore, NIH should study potential university, government, and industry

arrangements for the pooling and cross-licensing of genomic and proteomic patents, as well as research tools.

Ensuring the Public's Health
A few cases of refusals to license practices by some companies have generated controversy because of the potential adverse effects on public health. In the United States, courts have denied injunctive relief in cases where health and safety are an issue. Should the rare case arise in which restricted access works against the interests of public health, courts should follow legal precedents and allow the provision of products or services that the public needs, while awarding compensation to particular inventors for the use of patented material.

Gene-Based Diagnostic Testing
There is concern about independent validation of genomic- or proteomic-based test results. Patent owners may control access to genomic- or proteomic-based diagnostic tests and then prevent others from using the patented technologies to validate the results of clinical tests. This may cause problems and encourage patent owners to enter into licenses that will permit others to use patented technologies for the purpose of independently confirming the results of a diagnostic test. Owners of patents that control access to diagnostic tests should establish procedures that provide for independent verification of test results. Congress should consider whether it is in the interest of the public's health to create an exemption to patent infringement liability to deal with situations where patent owners prevent independent verification of their tests.

COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION

SHIRLEY TILGHMAN (Co-Chair), Princeton University
RODERICK MCKELVIE (Co-Chair), Covington & Burling
ASHISH ARORA, Carnegie Mellon University
HELEN M. BERMAN, Rutgers University
JOYCE BRINTON, Harvard University
STEPHEN BURLEY, SGX Pharmaceuticals, Inc.
Q. TODD DICKINSON, General Electric Co.
ROCHELLE DREYFUSS, New York University
REBECCA S. EISENBERG, University of Michigan
CHARLES HARTMAN, CW Ventures
DANIEL KEVLES, Yale University
DAVID KORN, Association of American Medical Colleges
GEORGE MILNE, JR., Radius Ventures, New York, NY
RICHARD SCHELLER, Genentech, Inc.
ROCHELLE SEIDE, Arent Fox LLC
ROBERT WATERSTON, University of Washington
NANCY WEXLER, Columbia University
BRIAN WRIGHT, University of California, Berkeley
ANNE-MARIE MAZZA, Study Director, The National Academies
STEPHEN MERRILL, Study Director, The National Academies

For More Information
Copies of *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* are available from the National Academy Press (NAP); call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP website at www.nap.edu. For more information concerning this project, contact staff at (202) 334-2200 or visit the Policy and Global Affairs website at www.nationalacademies.org/pga.