Intellectual Property: The Control of Scientific Information

Dorothy Nelkin

Summary. Control of scientific information is increasingly at the center of legal and administrative disputes, raising questions of sovereignty and secrecy, of proprietary rights over research. Disputes originate from efforts to extend the right of access to data at an early stage of research, from demands for information that threaten confidentiality, from proprietary interests in competitive areas of research, and from government restrictions on the free exchange of scientific ideas. They reflect policy changes with respect to information disclosure, university-industry collaboration, patent rights, and national security. A review of diverse situations that have led to disputes and of efforts to negotiate principles for controlling intellectual property suggests the problems of establishing such principles in the context of the changing role of science.

Who should control scientific information? This issue is at the center of a growing number of legal and administrative disputes. To whom do the data from federally funded research belong: the scientist who does the research or the government agency that pays for it? At what point in the research process are the data to be made available to interested citizens, competing scientists, or industrial firms? May the researchers themselves use their data and ideas in any way they choose?

Such questions have long been controversial because of the application of science to practical problems and its role in public affairs. They have become more urgent, however, as the gap between the production of knowledge and its application has narrowed. Related changes in policies concerning information disclosure, university-industry collaboration, patenting, and military security follow directly from the utility of research, turning scientific data and even ideas into "intellectual property"—something that is "owned or possessed" and therefore subject to competing claims (*1*).

Few principles exist to establish a definition of intellectual property. A congressional committee report has described the confused state of government information policy: the "profusion of inconsistent and often conflicting laws, policies and practices" (*2*). With few guiding principles, the struggle over control of scientific data and ideas has taken the form of discrete disputes in which all parties stake their claims in terms of moral rights and responsibilities: the "right to know," the "right to privacy," the "right to access," the "right to control one's own product," the "obligation to protect research subjects," and the "responsibility to protect the public interest."

Scientists who accept public funds are required by federal regulations to be accountable for the use of those funds, to give the funding agency access to their results as stipulated in a prior agreement, and to accept concomitant public disclosure. The federal agency's specific choice of funding instrument has itself a practical importance for the recipient's control (*3*). Except in the case of classified military research, scientists assume that data from projects funded by grants (as opposed to contracts or cooperative agreements) belong to the researchers. External controls on work done under grants are seen as a threat to the quality and integrity of research and an infringement on scientific freedom. In this context, applying concepts of "property" to scientific ideas is extremely controversial.

Much of the recent discussion about intellectual property in science has focused on the commercialization of biomedical research, but this is only part of a wider phenomenon. By describing diverse disputes over the control of research, I hope to suggest the broad range of situations in which questions of intellectual property have become important, the implications of recent changes in the relation of science to government and industry, and the problems involved in negotiating the principles of ownership and control (*4*).

Public Access versus Professional Control

In 1976 a group of physicians filed a request under the Freedom of Information Act (FOIA) for data gathered during a long-term clinical study of the effects of five diabetes treatment regimens, in which 1000 patients had been monitored over periods ranging from 5 to 8 years. A private consortium called the University Group Diabetes Program (UGDP) had conducted the study under the sponsorship of one of the National Institutes of Health (NIH). Under the terms of the grant NIH had the right to access to the raw data, but it never exercised that right.

The UGDP researchers found that certain regimens might increase the incidence of heart disease without any offsetting benefits. When they published these findings, the FDA recommended changes in the use and labeling of a particular diabetes treatment drug. An association of physicians, concerned lest a useful drug be removed unnecessarily from the market, requested access to the raw data and when refused brought suit (*5*). The U.S. Court of Appeals in 1978 ruled against disclosure on the grounds that the data, which were not actually in the possession of NIH, did not constitute "agency records," defined by statutory language as material that an agency has "created or obtained." In a dissenting opinion, however, Judge David Bazelon argued that federal funding of the research and reliance on the data for regulatory action were sufficient reasons to require disclosure and that, under FOIA, data underlying government actions must be open. In 1980 the Supreme Court upheld the ruling of the lower court, avoiding the policy issue concerning the public's right of access and bas-

The author is a professor at Cornell University in the Program on Science, Technology, and Society and the Department of Sociology, Ithaca, New York 14853.

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ing its decision on the narrow legal question of possession.

A case with a different outcome also turned on the principle of custody. In 1978 Milo Shannon-Thornberry completed data collection on the socioeconomic factors affecting infant feeding practices and the relative effect of bottle and breast on morbidity and mortality rates. A group of nonprofit church organizations had sponsored the research. Lacking the resources to convert the data to computer records, Thornberry enlisted the facilities of the Department of Health, Education, and Welfare's Center for Disease Control (CDC) to help in the tabulation. He agreed in return to make the survey material available to the federal agency. In September 1979 two manufacturers of infant formula, Mead-Johnson and Abbott Laboratories, requested the raw data. Thornberry objected. He had collected them with private financing and claimed prior rights to analyze and publish them. He feared that the intent of the request was "industrial sabotage" of research threatening to corporate interests. In fact, a division of Abbott later circulated to physicians a letter undermining the credibility of the research.

In April 1980 a federal district court held that the CDC's possession of the data and its involvement in the project defined the data as "agency records" (*6*). Although CDC's role in the research was mostly clerical, the court considered disclosure to be proper; it chose to avoid the policy question about the intent of FOIA requests.

In other cases the courts have taken a more substantive view of requests that threaten professional control. James Allen, of the University of Wisconsin, had been working on a long-term, federally funded study of the effect of dioxin on rhesus monkeys. In 1979 he presented preliminary results as testimony during a hearing of the Environmental Protection Agency (EPA) on the use of dioxin in commercial pesticides. After the hearing, Dow Chemical Company tried to obtain all the data from Allen's study, arguing that if results were made public the background data should be available as well. Allen objected, on the grounds that the work was not completed or properly analyzed and that the testimony was only a preliminary progress report. An EPA administrative law judge granted Dow's request and issued a subpoena, but Allen refused to comply, on the principle of the scientist's right to autonomy. Following this reasoning, a U.S. district court overturned the ruling, agreeing that disclosure of data to a company with vested interests could jeopardize a costly study and that the public interest was better served by withholding data until after peer review (*7*). This decision was upheld by a federal appeals court in 1982.

The right of public access to information is sometimes invoked to obtain copies of unfunded research proposals. Requests to NIH for copies of proposals increased from 300 in 1975 to more than 1600 in 1979 (*8*). Although only a few of these requests (11 in 1979) have been for unfunded applications, scientists are sensitive to the threat of disclosure and contend that this would jeopardize the grant evaluation process and allow plagiarism or the pirating of ideas. Ideas, the scientist's "stock in trade," are in their view analogous to trade secrets in industrial firms.

The Right of Access versus Obligations of Confidentiality

In 1976 the National Heart and Lung Institute (NHLI) of NIH supported a longitudinal study of the health history of individuals with certain medical profiles. The researcher maintained detailed personal records and, in compliance with the Privacy Act, submitted only the final report of his findings to NHLI. During the course of study an independent investigator requested access to the records in order to conduct his own research. NHLI allowed its contractor to decide how to comply with the conditions governing the disclosure of confidential personal information (*2*, pp. 9–10).

In other cases, however, federal agencies try to maintain greater control. For example, HEW funded a study by a private research organization, Minnesota System Research Incorporated (MSRI), to evaluate the accuracy of HEW project ratings. When interviewing the scientists who had rated the projects, MSRI researchers promised not to reveal their identity. HEW, however, asked for the computer tapes, which contained the names of the respondents. The investigators objected on ethical grounds, but HEW insisted that a researcher could not promise confidentiality without first obtaining written agency permission. Eventually MSRI released the tapes (*9*).

Conflicts over confidentiality are most common in medical or social science research in which personal information is gathered (*10*). Special problems arise in the study of deviant or politically sensitive groups. Federal agencies require that in research on crime, drug addiction, political protest, and mental illness guarantees be provided to protect research subjects who could be liable to legal pressures if their identities were revealed. However, release of personal data gathered in health and epidemiological research could be equally damaging to individuals (*11*). The right of researchers to protect their subjects is especially vulnerable when it conflicts with political or policy goals. For example, there is the well-known case of the political scientist Samuel Popkin, who was imprisoned for contempt of court in 1972 because he refused to give the names of the persons he had interviewed to a federal grand jury investigating the publication of the Pentagon papers (*12*). The case is not unique. One study found that between 1966 and 1976, 50 subpoenas were issued demanding revelation of the sources and subjects of research (*13*).

The principles governing confidentiality in research remain inconsistent. The National Research Act of 1974 contains provisions to protect the privacy of human subjects, but it does not protect them from subpoena by the courts; nor does the legislation protecting the privacy of medical information used in health research (*14*). Researchers seek immunity from subpoena in order to avoid compromising their sources of data, but access to those sources is often necessary for law enforcement or policy purposes, or simply in order to maintain accountability in competitive areas of research.

Competitive Secrecy versus Open Communication

In 1977 a man with leukemia donated a sample of the cancerous cells from his bone marrow to research hematologists at the University of California School of Medicine. The scientists succeeded in creating a new cell line that could be used to study leukemia. They sent a sample to a colleague, who discovered that the cell line produced interferon, the body's natural antiviral protein. That scientist sent his sample to another colleague, who worked at the Roche Institute of Molecular Biology, funded by the pharmaceutical firm Hoffmann–La Roche. He, in turn, used the sample to develop an optimal medium for the production of interferon. The biotechnology firm Genentech, under contract to Hoffmann–La Roche, then used the cells to

manufacture interferon genes, creating the potential for a profitable enterprise. There followed a dispute between the University of California and Hoffmann–La Roche over the ownership of the genes (*15*). The University of California claimed ownership, and the right to future royalties, as the institutional home of the scientists who had created the cell line. Hoffmann–La Roche also claimed ownership, and filed a patent application covering both the interferon and the gene splicing manufacturing process. Lawyers from the university protested, arguing that the firm had made unauthorized use of the material, taking commercial advantage of the open exchange of information and material among academic scientists.

This is but one of several disputes that may affect the practice of freely circulating materials and research findings among colleagues. Donald Kennedy, president of Stanford University, observes: "Scientists who once shared prepublication information freely and exchanged cell lines without hesitation are now much more reluctant to do so . . . the fragile network of informal communication that characterizes every especially active field is liable to rupture" (*16*).

Two decisions in 1980 brought these issues to public attention. First was the Supreme Court decision to allow the patenting of a genetically engineered bacterium (*17*). Second was the signing of the Patent and Trademark Amendment Act allowing universities, nonprofit institutions, and small businesses to apply for patents on federally funded research, the profits to be used to support further research (*18*).

Patents are specifically intended to avert proprietary secrecy as well as provide incentives for invention. But some fear that patenting possibilities in areas of basic science could also lead to closing of communication among researchers because of competition for patent priorities (*19, 20*). As universities seeking new forms of income and scientists attracted by possibilities of commercial development become directly involved in the industrial exploitation of research, tensions also develop between university adminstrators and faculty, between professors with commercial interests and graduate students whose careers depend on open discourse, and between federal and industrial research sponsors when there is a mingling of research support.

Tensions between commercial and academic interests are not new. Research cooperation between universities and industry flourished in the early part of the century, drastically reshaping the university system (*21*). Just as they are today, academics were ambivalent, welcoming such collaboration as a source of vitality but fearing its intrusion on academic freedom. Industry-university relations stabilized, however, through a system of contracts and cooperative agreements in engineering and the applied sciences. Scientists doing basic research participated mainly through individual consulting arrangements (*22*).

Today these traditional modes of interaction are changing. Ad hoc consulting arrangements have turned into equity participation in new venture-capital firms. In line with federal policy encouraging industry-university cooperation, universities are accepting collaborative arrangements in areas of basic as well as applied research. By the end of 1981, eight major agreements were either consummated or undergoing final negotiations.

National Security versus Scientific Freedom

In the summer of 1980, a computer scientist at the Massachusetts Institute of Technology wrote a proposal to work on the mathematical basis for developing computer techniques that would be impervious to code breaking. He applied for a grant from the National Science Foundation (NSF), which has routinely supported cryptography research. Since 1977 NSF has sent such proposals to the National Security Agency (NSA) for technical review because of their potential significance for foreign intelligence activities. That agency is responsible for the collection of intelligence information, does most of its own research, and has been increasingly uneasy about studies relating to its concerns but outside its control. This particular project was the first basic research to attract serious attention, and NSA wanted to assume part of the funding so that it could require review for military sensitivity prior to publication. Mathematicians working in this area were appalled at the idea that their work might be classified as unpublishable and therefore unavailable for public use (*23–25*). They negotiated a system of voluntary restraints in exchange for an advisory role.

The cryptography case must be seen in the light of two emerging trends: the trend toward extending national security controls to projects that are not sponsored by agencies concerned with military technology, and the trend toward applying such controls not only to hardware but to basic ideas and to "strategic information," that is, to information that if released could possibly harm the national interest.

Constraints on research of military significance are obviously not new. Under the Invention Secrecy Act, patentable discoveries may be placed under "secrecy orders" if disclosure is deemed detrimental to national security. This usually pertains to inventions developed by people working under defense contracts, but it has been more and more frequently applied to other inventions as well (*23, 26*).

Formidable secrecy controls also govern atomic research (*27*). Since World War II the federal government has maintained unambiguous authority to control all such research within or outside government laboratories. Information in this area is "born classified"—it is an official secret from the moment it exists. With the commercial development of nuclear energy, some provisions of the Atomic Energy Act of 1964 were relaxed. However, federal controls over access to information in this area give government agencies all proprietary rights.

The International Traffic in Arms regulations (ITAR), authorized by the Arms Export Control Act, provide that publication of unclassified information that can advance any significant military application requires prior approval by a cognizant agency. This provision is so inclusive as to allow flexibility of interpretation with respect to research (*28*).

Several incidents suggest the trend toward more rigid interpretation of such regulations. In the winter of 1980 a series of restrictions was imposed on scientific exchange (*29*). The Department of Energy issued an order requiring government clearance of any communication between its contractors and Soviet scientists. The Commerce Department forced the American Vacuum Society to withdraw its invitation to Soviet bloc scientists to attend an international conference on magnetic bubble memory devices. The State Department refused to issue visas to eight Soviet scientists who had applied to attend a conference on lasers and electro-optical systems. Also, it sent letters to university science departments asking them to restrict the movements of Chinese students and visitors.

Some proposed bills would impose further restrictions. One would require academic institutions accepting foreign students for study in certain scientific

fields to submit detailed information on what they would be learning, whom they would work with, and where they planned to travel. More threatening is a legislative proposal to extend to ideas the provisions of the Arms Export Control Act which require a State Department license for exporting "critical technology" (*30*). Scientists who want to publish or lecture overseas on any subject relating to a technology listed on the U.S. Munitions List would have to obtain a prior license, and would bear the burden of proof that they would not be disseminating ideas harmful to our national security. The scope of restricted subjects could include research related to computers, lasers, and cryptography, but the list is far from clear. This and a similar revision of the Export Administration Act have remained in the House Foreign Affairs Committee. They are obstructed by questions of constitutionality and superseded by the Executive order that greatly increases the government's power to classify research not clearly related to national security. The Executive order omits the critical requirement established during the Carter Administration that decisions imposing secrecy must be balanced against the right to know, and mandates that "if there is reasonable doubt about the need to classify . . . the information shall be considered classified."

Negotiations

Scientists and their research sponsors are struggling to negotiate practices and articulate principles that would clarify questions of control in terms appropriate to the growing importance of scientific information. Open access to information serves the public interest, being consistent with the democratic values of open government and facilitating fiscal and management control over governmentally funded activities (*31*). But unlimited access may threaten the scientific process. At what point in the course of research should data be released? Are ideas to be publicly available in their tentative stages? Are data tangential to a project to be available as well? How can the integrity of long-term projects such as clinical trials be maintained while demands for public review are being satisfied?

Such questions have elicited efforts to define the terms of access under the FOIA. The director of NIH, for example, sought a specific exemption for data from ongoing clinical trials and epidemiological studies, although requests for such data have been rare. He brought the matter before the Ethics Advisory Board of HEW, arguing that premature release of data from clinical trials could impede the randomization necessary in the trials, and in the case of epidemiological studies could lead to publicity about misleading trends that would unduly alarm the public. He hoped to establish the principle that data that are preliminary, incomplete, or not yet validated should be exempted from FOIA because the public interest would thereby be better served. The Ethics Advisory Board recommended legislation to provide a limited exemption (*32*).

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research reviewed the implications of using FOIA to obtain information about research protocols and designs. The commission concluded that HEW's policy of releasing data only after funding is awarded is necessary in order to protect peer review procedures, and recommended legislation to ensure a continuation of the existing practice (*33*).

As a result of these various pressures, it is now proposed, in a bill to revise FOIA, that research be added to the other matters, such as trade secrets, that are exempt from compulsory disclosure.

Professional societies are establishing their own special committees to respond to questions of intellectual property and are experimenting with codes of ethics that include provisions about disclosure. Individual scientists have proposed research agreements that would confer a status of "executive privilege" on research in order to protect confidentiality. However, such agreements would not be legally binding. Usually scientists protect information by practicing "defensive record keeping," but they have also sought protective legislation (*34*). For example, in 1980 a bill was introduced in Congress on privacy of research records (S. 867 and H.R. 3409) which was intended to exempt researchers from subpoenas that would violate the privacy of their subjects. The subjects of research on drug and alcohol abuse are already protected; this bill would have extended such statutory protection to all federally funded research. Legislation might have provided some clarification of the problem of confidentiality, but the bill never got as far as a hearing.

A remarkable number of studies and proposals have tried to resolve the problems of proprietary secrecy and academic autonomy associated with increasing industry-university collaboration. Universities are negotiating limited partnership arrangements with industries that would yield economic benefits yet allow them to maintain internal control over research practices and to publish in areas where proprietary secrecy could pose serious constraints. An NIH working group has recommended that all institutions receiving research funds have a written patent policy including provisions for resolving proprietary disputes (*20*). The Recombinant DNA Advisory Committee (RAC) of NIH has revised its guidelines in order to protect proprietary information while allowing the necessary review. These guidelines allow access to research information only to committee members and staff, who must pledge confidentiality and maintain locked files.

Military efforts to extend control over the disclosure of nonclassified research are also under negotiation. The mathematicians concerned about control of cryptography have established a system of voluntary restraint. Researchers have agreed to submit their papers to NSA for review prior to publication, and NSA in turn has agreed that, if there are potential security problems, it will consult an advisory group before blocking publication (*25, 35*). Vice Admiral Bobby Inman, seeing direct contradictions between scientific practices of open publication and national security needs, proposes extending this system of voluntary restraint to other fields. The threat of such restraints is forcing a sharpening of distinctions between basic and applied research, although convergence has served science well.

Most challenges to scientific discretion end in appeals for statutory protection, based on an assumption that the researcher has the "right" to assess the terms of disclosure. Such protection would require a more coherent effort to clarify the social role of scientists and the nature of research that is worthy of protection. Should criteria for protection be based on the credentials of scientists or on their sources of support, on the methodology of a project or on the social purposes to which it may be applied? Under what conditions would mandatory disclosure or, conversely, secrecy be appropriate?

At present, the scientific response to such questions is curiously ad hoc. Arising from individual incidents, the efforts to negotiate control over research are often inconsistent. Scientists appeal for statutory protection from the disclosure requirements of FOIA, but in doing so they help to weaken legislation that encourages open exchange of information.

They seek greater military support of research but are outraged by national security restraints. They emphasize the useful application of basic research but then draw distinctions to avoid external control. Good reasons underlie each response, but such contradictions may make science more vulnerable to control. For example, in justifying national security constraints, Inman has called scientific claims of freedom "disingenuous" in the light of the trade secrecy restrictions that academics routinely accept as part of their industrial ties (*36*).

The response of scientists rests on the principle of sovereignty and on the belief that the public interest is better served if research is under scientific control. It rests on a notion that scientists have a "right" to control their research, that autonomy is necessary in order to maintain integrity, to avert the misinterpretation of premature data, and to protect their "stock in trade." Those who request data claim the "right to know" as an essential condition of democracy. Government agencies claim the right to information as part of their obligation to assure responsible use of federal funds, to meet policy goals, or to maintain national security or law enforcement in the public interest.

In today's political context, resolution of these conflicting claims leans toward greater constraints on freedom of information—constraints apparent in the weakening of FOIA, the extension of national security classification, and other restrictions on open communication, some of which protect scientific sovereignty and some of which threaten it.

Contradictions persist, reflecting the deep ambivalence within science about its cognitive and practical dimensions. Is science the pursuit of truth or the pursuit of useful knowledge, a carefully disciplined process or a professional and instrumental activity? The ambivalence so apparent in the disputes over the control of research suggests that there have been significant changes in the social role of science and in the importance of research. Indeed, these disputes are part of a larger struggle to renegotiate relations between science and the public that were established at a time when science was a very different social enterprise.

References and Notes

1. The term "intellectual property" is commonly used to refer to intangible property rights in trade secrets, patents, or copyrights. I am using it more broadly as "an aggregate of rights in the results of creative efforts of the mind" (*Webster's New International Dictionary*, ed. 2), and focusing on the question of control that is the most critical and yet ambiguous aspect of the concept of ownership in science.
2. U.S. House of Representatives, *Lack of Guideline for Federal Contract and Grant Data* (29th Report by the Committee on Government Operations, Government Printing Office, Washington, D.C., 1978).
3. P. Raven-Hansen, "*Quid pro quo* for public dough," address at the New York Academy of Sciences, New York City, 4 March 1981.
4. I shall concentrate on basic research, excluding those areas of military and applied industrial research that are indisputably subject to proprietary secrecy or military classification. However, it is important to note that the debates about disclosure of scientific information take place in the context of a broader debate over the exemption of trade secrets from the Freedom of Information Act. This debate has come to focus on the proprietary status of test data on health and safety. See T. O. McGarity and S. Shapiro, *Harv. Law Rev.* **93**, 831 (1980).
5. See *Forsham* v. *Califano*, 587 F. 2d 1128 (D.C. Cir., 1978); *Forsham* v. *Harris*, 445 U.S. 169 (1980).
6. *St. Paul's Benevolent Educational and Missionary Institute et al.* v. *The U.S. of America et al.*, C 79-2047A (N.D. Ga.) 8 January 1980 and 29 April 1980.
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8. B. Hosford, "FOIA Requests at NIH, 1975–1979" (National Institutes of Health, Washington, D.C., 1980).
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15. N. Wade, *Science* **209**, 1492 (1980).
16. D. Kennedy, "Health research: Can utility and quality co-exist?" lecture at the University of Pennsylvania, 6 December 1980.
17. *Diamond* v. *Chakrabarty*, 79-136, U.S. Supreme Court, 16 June 1980.
18. Public Law 96-517, 12 December 1980.
19. For the intent of patenting, see R. B. Stevenson, Jr., *Corporations and Information* (Johns Hopkins Univ. Press, Baltimore, 1980); for concerns about effect on secrecy, see (*20*).
20. Advisory Committee to the Director of NIH, *Cooperative Research Relationships with Industry: NIH Patent Policy Initiatives* (National Institutes of Health, Bethesda, Md., 1981).
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27. _____, "Information, secrecy, and atomic energy," unpublished (1981).
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29. See summary by L. Lubrano, *Sciences, N.Y. Acad. Sci.* **11**, 12 (1971).
30. 22 U.S. Code, sect. 2778.
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34. P. Nejelski, *Soc. Probl.* **21**, 3 (1973); "The rule of law and social research," paper presented to the Conference on Solutions to Ethical and Legal Dilemmas in Social Research, Washington, D.C., 23 February 1978. Nejelski argues that legislation is the only effective protection and sees a model in the legal decisions allowing journalists to protect their sources.
35. G. B. Kolata, *Science* **210**, 511 (1980).
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