chapter 8

Technology Transfer

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chapter 8

Technology Transfer

"The politics of knowledge—the question of who owns and controls the distribution and use of scientific information—is by no means a new issue. The pure scientist working in an ivory tower has long been extinct. "

Dorothy Nelkin, Science ***as Intellectual Property: Who Controls Research?*** (Washington, DC: American Association **for the Advancement of Science,** 1984), p. 92.

The economic impact of genome projects will depend on how many new products and services are created by them. Some large scientific projects such as space programs and electronics research facilities have been justified by their potential for spinning off technologies. The magnitude of such spinoffs is unpredictable, however. Often, there emerge useful products that could not have been foreseen IHeilbron and Kevles, see app. A], Given the many surprises in molecular biology over the past decade, it is impossible to predict exactly how genome projects will result in products, but they undoubtedly will yield many new applications in pharmaceuticals, agriculture, and other industrial sectors. Uncertainty about the magnitude of economic impact means that genome projects cannot be justified purely as an economic investment. As the projects go forward for scientific and medical reasons, however, it makes sense to ensure that their results are fully used. The process of converting scientific knowledge into useful products is ***technology transfer.***

The Federal Government influences the efficiency of technology transfer through its research and development policies. Government has traditionally supported research that will have large but unmeasurable noneconomic benefits (e.g., research aimed at improving health as a value in itself rather than simply disease impact measured in dollars) or that is too risky for individual firms to support (e.g., projects that are expensive, highly uncertain in outcome, or long-term). Arguments for increased Federal support of biomedical research since World War II have generally emphasized improvements in health. Economic arguments for increased biomedical research funding have typically been analyses of economic drag–how much the Nation could save by avoiding disability or disease (18). This argument is changing **to** concern for efficient translation of science into products. Policymakers are shifting their attention to technology transfer as products derived from molecular genetics find their way to the marketplace, international trade imbalances worsen, and rising deficits intensify scrutiny of Federal budgets.

A major effort is underway in many developed and some developing nations to target biotechnology for investment because it is considered particularly likely to produce economic benefits (3, 16,19,23). Most foreign governments' efforts to promote biotechnology include strategic planning of national research programs and encouragement of research and development in private firms (e.g., tax incentives, subsidies for industrial research centers, business grants, or government risk capital). The United States has no deliberate Federal policy to encourage biotechnology per se (16,19,23), although legislation introduced late in the first session of the looth Congress would create a national biotechnology policy board.

Most genome projects could produce both direct and indirect economic benefits. Some projects are expected to yield directly marketable products (e.g., DNA sequenators, analytical instruments, DNA probes for diagnostic tests). Others would accelerate development of products (e.g., maps, repositories, and databases).

Different groups have divergent concerns about technology transfer. Scientists fear that corporate participation will inhibit the free flow of information and impede scientific progress. Policymakers want to ensure that a large Federal investment in genome projects is translated efficiently into new products and services, ultimately creating new jobs and other economic benefits. They are wary of projects in which U.S. taxpayers will fund

research that is commercialized and used by foreign interests. In this view, foreign governments should support an equitable fraction of basic research, and American investments should not allow jobs and profits to migrate abroad. Industrial representatives want a say in planning research programs and access to scientific results as they are produced. Individual companies wish to ensure that any funds they invest will earn sufficient returns.

Congress could encourage technology transfer by funding personnel exchange among government, academic, and industrial sectors, with minimal bureaucratic strictures, and by supporting symposia, journals, and other modes of information exchange. When advisory committees are formed to guide Federal genome projects, industrial representatives could ensure that projects are planned with an eye to economic exploitation. These options are covered in chapter 6. The remaining options relate to protection of inventions resulting from federally funded research, discussed below.

PATENT AND COPYRIGHT POLICIES

Ideas and know-how—intellectual property—are granted many of the same legal protections as tangible private property. Intellectual property law traces its roots directly to the U.S. Constitution, which authorizes the Federal Government "to promote the Progress of Science and the useful Arts, by securing for limited times to their Authors and Inventors the exclusive Right to their respective Writings and Discoveries," The purpose of intellectual property protection is to encourage inventors and discoverers to share their knowledge, while ensuring that they benefit from the fruits of their labors. Legal protections balance the social good stemming from wide disclosure of new knowledge against individuals' or companies' rights to gain from what would not have existed without their efforts.

Three types of intellectual property protection are relevant to discussion of the technologies likely to emerge from genome projects: patents, copyrights, and trade secrets.

Patents

patents grant inventors the right to exclude others from producing, using, or marketing their inventions (as defined in the patent claims) for a specified period. The purpose of patent law is to give inventors an incentive to risk their time and money in research and development, while requiring public disclosure. Patent laws in different countries vary in degree of protection, enforcement, penalties for violation, and criteria for approval. In the United States, the period of protection is 17 years, with extensions for pharmaceuticals to cover some of the delay imposed by regulation. Patents apply to inventions, but not to ideas, mathematical formulas, or discoveries of preexisting things. A patentable invention must be new, useful, and not obvious. A patent holder can permit others to use or make the invention by licensing it.

Profit is only one of many motivations for patenting an invention. Another is to maintain control over it. Leo Szilard filed a patent on the process of nuclear fission, for example, hoping to bring it to the attention of military authorities in the United States and Great Britain (12). Cyclotrons used in nuclear physics were patented to ensure their proper medical applications, yet this did not inhibit research (in fact, most physicists were not even aware of the patents) IHeilbron and Kevles, see app. A]. The Rockefeller Institute patented the sphygmomanometer (blood pressure cuff) to ensure that clinicians would have ready access to it and that later discoverers could not limit its use (11). Nonprofit organizations supporting genome projects are likely to encourage patents when they would ensure broad public use (9).

U.S. patents are obtained from the Patent and Trademark Office in the Department of Commerce (other nations have analogous institutions). The patentability of inventions is initially determined by this office. The scope of protection and more refined factors for granting patents are defined by case law, when patents are challenged

in court, The principles for determining patentability do not depend on any particular type of technology, but interpretation of them does. Uncertainty about the patentability of inventions is greater in biotechnology than in most other areas because the techniques are new and complex. Interpretation of criteria for granting patents, defining the scope of patent claims, and determining what constitutes infringement have not been clarified by case law, because the case law does not yet exist.

Patent Policies for Federally Funded Research

Uncertainty about patentability need not paralyze research efforts, because interpretation of patent law does not interfere with most federally supported research (as explained below). Patent policies of Federal agencies will nonetheless influence how genome research is commercialized, and these patent policies have changed dramatically over the past decade. The changes are intended to promote commercial application of federally funded research by permitting private ownership and control of its results. The reasoning is that research will be more broadly disseminated and effectively used if those who conduct it are granted title to the patents on resulting inventions, thus providing an incentive to commercialize the inventions [Rosenfeld, see app. A].

Changes in patent policy resulted from studies showing that, while the Federal Government held title to roughly 28,000 inventions in 1975, fewer than 5 percent had been licensed to businesses (15). The Patent and Trademarks **Amendments of 1980 (Public Law 96-517) were passed to grant title to small businesses and nonprofit organizations funded to do research by the Federal Government. These were further amended in the Trademark Clarification Act of 1984 (Public Law 98-620), most significantly by removing restrictions on licensing. Regulations implementing these laws were made final by the Department of Commerce in March 1987.**

The policies applying to small businesses and nonprofit organizations were extended to large businesses, with some exceptions, by a memorandum from President Ronald Reagan dated February 18, 1983, The Technology Transfer Act of 1986 (Public Law 99-502) permitted new licensing and joint venture arrangements, and granted agencies authority to form consortia with private concerns. Executive Order 12591, issued by President Reagan in April 1987, encouraged technology transfer of federally funded research. The order was based on existing statutes and promoted consortium formation, exchange of research personnel between government laboratories and industrial firms, special technology transfer programs at federally owned laboratories, and transfer of patent rights to government grantees and contractors,

The policies embodied in these statutes, regulations, and executive orders constrain the authority of Federal agencies to force sharing of data if sharing would conflict with recipients' taking title to inventions [Rosenfeld, see app. A], The government can override recipients and take title to patents only in special situations. One of these is when an agency determines that retaining title '(will better promote the policy and objectives" of the patent statutes. This clause has been narrowly interpreted and has rarely been used by the research agencies involved in genome projects IRosenfeld, see app. **Al.** The Federal Government can also impose licensing requirements to '(alleviate health and safety needs," "meet requirements for public use specified by Federal regulations, " or meet "certain statutory provisions requiring products to be manufactured in the United States." These provisions have also been narrowly interpreted and impose such a daunting burden of proof on agencies that they are unlikely to be used. They could conceivably be invoked if patent rights interfered with the pooling of data that must be collective to be useful or if clinical benefits were delayed (e.g., slow commercialization of genetic tests or therapies), but only if problems were severe and obvious.

Federal research agencies' patent policies need not unduly slow exchange of information. The degree to which information flow is impeded will depend on when grant recipients and contractors file patent applications. Many genome projects will result in patentable inventions, particularly those focused on technology development. Recipients of Federal funds may follow one of three courses of action: file applications early and subsequently

release data; file early and do not take extra actions to release data (relying on the patent process to do so); or decide not to patent.

Filing patent applications early and publishing data soon thereafter are optimal for encouraging rapid dissemination of knowledge, protecting inventors' rights, and preserving economic benefits in the United States. Early patenting and subsequent disclosure would release data for public use but would help inventors maintain control of their inventions and assure them and their sponsoring institutions of any financial rewards. Early patent application would also protect the Nation because statutes give a preference to U.S. manufacture of any resulting products or services. Early patent application not followed by special efforts to disseminate data would ensure benefits for the grant recipient or contractor but would needlessly delay exchange of useful information-patents are often not published for several years, and it has taken over 7 years for some biotechnology patents to be awarded.

Investigators may decide not to apply for a patent because they wish to avoid substantial legal costs and bureaucratic entanglements or because they believe that science should not become commercially oriented. This can make new methods freely available to all, but it can also inhibit full exploitation of an invention. It is also against the intent of Federal statutes, which require recipients of Federal funds to report patentable inventions. An inventor can lose control of an invention if he or she does not file a patent and another inventor does so. A product or process that is not patented is unlikely to be used commercially, because any firm investing in manufacture will want a guarantee that its investment will be protected. Failure to patent also invites foreign exploitation of research funded at U.S. taxpayers' expense: Patent rights could be claimed by a foreign company, research institution, or individual; U.S. firms would not be given manufacturing preference; and the US. inventor could be prevented from use of the invention. Export of economic benefits has occurred frequently in biological sciences when initial discoveries have not been patented. Penicillin was discovered in England, for example, but the patent was obtained by U.S. corporations. The cell fusion process for making monoclinal antibodies was developed in London, but many of its applications were exploited first in the United States. In both cases, the United Kingdom claimed the Nobel Prize, but the United States reaped most of the economic benefits.

Federal agencies and Congress may wish to oversee patent practices of grantees and contractors closely to ensure that patents are filed early and data exchanged soon thereafter. Disclosure of ***data*** should not be long delayed by policies designed to encourage patenting of inventions, because data per se are not inventions eligible for patent protection. There is a gray area, however, between invention of new methods and the data that result from using them.

Scientists may be reticent to disclose details of methods used to generate data if doing so endangers patentability. An invention must be novel to be patented: that is, it must not be widely used by parties other than the inventor for more than one year, and publication of the method cannot precede filing the patent by more than one year. (Some foreign countries do not permit even the one-year grace period.) If investigators are uncertain whether disclosing details of method would threaten a patent, they may choose not to publish those details. Uncertainty over patentability can indeed inhibit the free exchange of information. It has led one commentator to list three possible ways of altering patent laws: 1) making the definition of novelty more flexible; 2) establishing an intellectual property protection that is analogous to but more limited than patents and that requires less rigorous proof of novelty and nonob - viousness; or 3) legislating special intellectual property protections for biotechnology (8). Further study is needed "to determine whether and how biotechnology demands special treatment as intellectual property before legislative reform will be in order" (8). This suggests that patent policies might be high on the agenda for congressional oversight but low on the legislative calendar.

Filing patents early and then disclosing the results could worsen an already considerable backlog of pending patents. Approximately 7,000 biotechnology patents have been filed at the Patent and Trademark Office and await final action (20). If the benefits of patent protection are judged im-

portant by Congress, then one option would be to increase the resources in the biotechnology sections of the Patent and Trademark Office. This could include higher salaries, more opportunities for training to keep abreast of technological developments, easier access to technical databases, and more examiners. Increased resources could not only reduce uncertainty by diminishing the backlog of pending patents, but also increase the attention devoted to each application and reduce subsequent litigation.

Patent Policies at Research Agencies

The Department of Commerce recently promulgated final regulations for Federal agencies to use when funding research at small businesses, universities, and nonprofit organizations [37 CFR 401]. While these regulations, issued in March 1987, have had little time to take effect, the National Science Foundation (NSF) and the National Institutes of Health (NIH) have followed similar policies since the late 1970s,

The General Accounting Office found that university administrators, industry representatives, and small businesses all reported a "significant positive impact on research and innovation" from taking title to inventions that resulted from federally funded research, University and industry officials also reported benefits from the 1984 law that removed licensing restrictions (15). Agencies likewise reported a generally positive assessment, with greater potential for licensing patents than when title was retained by the Federal Government.

The situation at the Department of Energy (DOE) is more complex. A substantial fraction of DOE research funding goes to national laboratories, which are owned by the Federal Government and operated by private contractors. At most of the laboratories, the contractor can elect to take title to inventions. Title rights are restricted, however, at facilities that conduct research on weapons and naval propulsion systems. This could prove relevant to genome projects because several of the groups that have been directly engaged in DOE's Human Genome Initiative are located at laboratories with restricted title policies—namely, Lawrence Livermore National Laboratory and Los Alamos National Laboratory, both operated by the University of California. Regulations state that limitations on the contractor's right to take title should be restricted to '(inventions occurring under" naval nuclear propulsion or weapons-related programs [37 CFR Part 401.3(a)(4)]. This should permit the contractor to take title to inventions from human genome projects because the projects would not be conducted under restricted programs, even at the affected laboratories. Negotiations between DOE and contractors are more complicated, however, when restrictions differ among programs at the same facility. Legislation has been proposed to mandate patent policies for genome projects at the national laboratories; the policies would be modeled on those of other research agencies.

The regulations and executive orders implementing patent policies at research agencies are quite recent. It would be premature to alter those policies fundamentally until the results of current law can be assessed (with the possible exception of DOE policies regarding national laboratories, noted above).

There are additional roles for Congress. First, Congress could monitor the practices of Federal agencies and funding recipients to ensure that the intent of existing statutes is carried out. Second, Congress could increase resources to the Patent and Trademark Office to enable more efficient processing of patents. Third, Congress could increase resources for universities and other recipients in order to manage patent filing in the United States and abroad. Finally, Congress could ask agencies engaged in genome projects to specify their patent policies more clearly, At present, written material on patent policies at NIH, DOE, and NSF is difficult to obtain, and there is no single source for information on patent policies at all agencies involved in genome projects [Rosenfeld, see app. A]. The interagency nature of genome projects means that recipient institutions will often be funded by more than one agency. A clear presentation of patent guidelines at various agencies, with explanations of the advantages of early patent filing and the implications of doing so (and not doing so), might diminish confusion and promote commercial application.

Copyrights

Copyright law is intended to protect works of authorship. It has traditionally been applied to works of art, books, and articles but has had to adapt to technological change. Copyrights now extend to computer software and electronic entertainment media, for example (6, 17). Copyright is intended to protect the ***expression*** **of** ideas, not the ideas themselves—a difficult but crucial distinction.

The Copyright Act of 1976 is the most recent statute relevant to genome projects, extending protections to nontraditional media such as computer software. The extensions may also prove relevant for research in molecular biology (6). Case law has evolved doctrines to test the distinction between idea and expression and to define the scope of protection. An author can prohibit others from copying his or her book, for example, but the concepts and methods described in the book are not protected. Arguments have been made that copyright could apply to DNA (6), but this line of argument is not widely accepted and the scope of protection (if it exists) is quite narrow (5). The ability to copyright a native DNA sequence derived from a human chromosome or other natural source is particularly uncertain (5). A preliminary communication from the Copyright Registration Office indicates that such sequences would not be accepted, although the book or printed map containing them—the particular expression of map or sequence data—would (10).

Even if DNA maps can be copyrighted, such copyrights are unlikely to inhibit research substantially. In normal circumstances, obtaining a copyright does not require extra time and is thus not a justification for delaying disclosure of results. A company could charge for access to map or sequence information in much the same way that commercial databases charge for information sharing. Access and service charges are not new—molecular biologists routinely pay for services that are less expensively or more rapidly performed by others. They buy copyrighted books and read copyrighted journals. Many materials used in biological research (clones, enzymes, chemicals) can be made by individual investigators, but it is easier to purchase such materials from a company set up to make them.

The type of research conducted by a private company engaged in mapping and sequencing DNA would be feasible in a large number of laboratories. Copyrights would not prevent investigators from using ***information*** published or otherwise provided by a company or from duplicating the work. A company that has developed extensive map and sequence information would either charge so little that it is cheaper for a researcher to obtain it from the company than to do the work, or the researcher would in fact repeat the work. In either case, the community of researchers is no worse off than if the company had not mapped or sequenced.

If copyright practices prove to impede research, then agencies can take steps to correct the deficiencies. Agencies have much broader discretion for copyright policies than for patents IRosenfeld, see app. A].

Trade Secrets

Information held by one company that is useful in its business and unavailable to competitors is called a trade secret. Trade secrets can be protected from misappropriation—that is, improper disclosure–through the courts, which award monetary damages for unauthorized use. A trade secret must be in continual use, be well established in practice, and have actual or potential commercial value (19). The holder must take steps to guard it. Trade secrets do not involve slow and costly legal steps for registration, their duration is not limited by law, and they need not meet patentor copyright criteria. Uncertainties about patents and copyrights are not relevant (although legal criteria for protection under trade secret laws must be met). Trade secret protections are principally secured under State rather than Federal laws, and there is some variation among the States. Trade secrets have limited scope: In a rapidly moving field they may not last long. Trade secret laws cannot ensure returns on a research investment if another inventor discovers the secret method or finds a new way to do the same thing. Protection does not apply, even if competitors figure out the secret by examining a product (reverse engineering). Most important, trade secrets must be kept secret. This would be quite difficult to justify for federally funded research.

The scientific equivalent of a trade secret is nondisclosure. This is referred to pejoratively as sitting on data and is widely viewed as improper beyond the period needed to confirm accuracy of results and take advantage of a lead for further research. The period of nondisclosure varies widely among researchers, even those in the same field, Researchers who share data and materials early and freely are widely praised, such as the many collaborators who worked to find the muscular dystrophy gene (see ch. 3). But nondisclosure—for a few months to a year—is not uncommon in order to maintain a research advantage or to establish first discovery, even in research leading to Nobel Prizes (or perhaps especially in such research) (21,22). Permanent nondisclosure of an important result is, however, inimical to the purpose of scientific inquiry—the discovery and dissemination of new knowledge.

Nondisclosure is of particular concern when the results must be pooled in order to be useful (e.g., maps derived from data contributed by various groups). The need for pooled data can create a situation known as the prisoner's dilemma: when cooperation of all parties yields the maximum benefits, but one party can benefit if he does not cooperate and the others do, (So called because prisoners planning a jail break all benefit from cooperation, but one stooge can benefit individually by telling the guard of the plans.) An investigator searching for the location of an unknown gene stands to gain if other groups with markers make them freely available but he does not. He can then use both his and others' work to speed the search, while denying others access to his markers. Similar situations will arise in connection with submitting information to databases, sending materials to other researchers or central repositories, and other cases directly related to genome projects. Agencies will need to monitor the free exchange of data and materials, particularly when the efforts must be collective, and take steps to correct inequities. The need for joint efforts highlights the importance and fragility of collaborative institutions such as the Center for the Study **of** Human Polymorphism (CEPH) (see ch. 7).

Many **journals have** either explicit or unwritten policies that research data and materials described in an article must be made available to other researchers at the time of publication. Researchers preserve their option for exclusive use from the time of discovery until publication. Many scientists make materials available even before publication, which can require many months. Linking availability of materials to publication is a powerful mechanism, because one measure of scientific prestige is priority—who discovered something first. Priority is generally determined by date of publication. In large collaborative scientific projects, mechanisms have evolved to permit scientists time to pursue hot research leads while ensuring that others gain fair access. (CEPH'S policy of sharing one set of data only among collaborators and making another set publicly available is an example.)

An informal policy of disclosure operates in Federal agencies through the process of peer review, If a researcher is known to hoard data—and such information spreads rapidly through scientific communities—then proposals submitted by that individual are unlikely to be given high priority by study sections (7). Review groups withhold support from research whose results they cannot see. This mechanism is slow—it can only be used when a grant is up for renewal, every 3 years or more—but it can be quite effective. If further measures are needed, Federal agencies could require submission of materials and data—map positions or DNA sequence data, for example—to the appropriate database. Such a policy would not be easily enforceable, however, and would be constrained by investigators' patent rights. Some journals now require submission of DNA sequences in proper form to GenBank" or its sister database in Europe at the time a paper is accepted. Agencies could devise incentives to make contribution of data and materials attractive, an alternative that is more easily implemented and less politically troublesome than negative sanctions. Those submitting data to CEPH, for example, benefit from knowing the position of their markers relative to markers found by others. Persons managing the DNA sequence databases have contemplated giving researchers a similar incentive,

Federal agencies have substantial power to require disclosure when it does not impede grantees' and contractors' intellectual property rights. Grant recipients and contractors need ample time to file patent applications, but legal protections

of intellectual property are unlikely to inhibit agency policies promoting disclosure, particularly when broad access to data is necessary to fulfill the agency's mission.

INTERNATIONAL TECHNOLOGY TRANSFER

Human gene mapping is inherently international in scope. Recent breakthroughs in assembling rough genetic maps, for example, have depended on an international collaboration of investigators from Europe, North America, and Africa using family data from four continents. Several current technologies for sequencing and physical mapping were developed in the United Kingdom and other European nations, not the United States; however, recent years have seen increased emphasis on retaining the economic benefits of federally funded research for the United States.

International technology transfer is the movement of inventions and know-how across national borders. Concerns about international technology transfer fall into four areas: economic benefits, humanitarian and scientific benefits, national prestige, and military applications.

Economic Benefits

Concerns about economic implications of international technology transfer focus primarily on the export of jobs and services generated by research funded at public expense, Policies to combat this fall into three main areas: patent policies, restrictions on flow of information and materials, and promotion of domestic technology transfer so that benefits remain within national borders,

The patent policies described above have several provisions on international technology transfer that are relevant to genome projects. For foreign recipients of Federal funds or those subject to a foreign government, agencies must consider whether the recipient's government or company enters into international cooperative funding agreements on a "comparable basis" and whether the recipient's government protects U.S. intellectual property rights [Executive Order 12591, Apr. 10, 1987]. Recipients of Federal R&D funds must ensure that the products of the invention will be "manufactured substantially in the United States" [35 U.S.C. 204]. Since jobs and economic wealth are linked more tightly to manufacturing than to initial research and development, even foreign-held U.S. patents resulting from Federal funding would have economic benefits in the United States. Moreover, Federal agencies are not required to grant patent rights to foreign recipients or those subject to control of a foreign government, even if they are universities or nonprofit organizations [37 CFR 401.14(a)(l)]. Foreign recipients are thus managed differently than their U.S, counterparts. Agencies could conceivably require foreign recipients to assign title to the U.S. Government or require that U.S. research partners take title,

Exploiting federally funded research inventions abroad will usually entail seeking foreign patents. Several international conventions govern patents, but conditions for granting patents differ among nations. The United States permits a grace period of one year from the date of publication to file a patent application, for example, but many other governments do not. If investigators wish to ensure worldwide patentability, therefore, they must file foreign patents before publication, The period of patent protection also differs. Researcher institutions accepting Federal funds must know about these and other differences when making decisions about foreign patents, Disseminating knowledge about such differences could be encouraged by research agencies in concert with the Department of Commerce. Agencies could also encourage institutions receiving Federal funds to pursue foreign patents.

The current necessity for filing patents individually in many countries is expensive and wasteful for all nations. International patent policies have been discussed several times at meetings of the Organization for Economic Cooperation and Development. Attempts are being made to harmonize international practices (14).

Humanitarian and Scientific Benefits

The humanitarian and scientific benefits of genome projects will be great. The United States has consistently performed a significantly higher fraction of the total mapping and sequencing effort than any other nation (see ch. 7). The knowledge resulting from these efforts has been freely shared with the rest of the world, to the benefit of citizens of all nations. The scientific knowledge generated at Federal expense since World War II may well prove to be one of the most significant international contributions of modern American culture.

Imposing restrictions on the flow of information and scientific materials from U.S. researchers to researchers abroad would be politically troublesome and technically difficult. Details of what to share and what to restrict would be difficult to describe in advance, and policies restricting the flow of data are against scientific traditions, which transcend national borders. Withholding map locations and DNA sequence information would be a violation of scientific ideals, particularly when such information could be clinically useful. Unilateral restrictions imposed by the United States would invite reciprocation, to the detriment of worldwide scientific progress.

The same tradition of free international exchange does not necessarily apply to the exchange of services and products—for example, mapping services, instruments, automation equipment, and reagents—which is governed more by international trade agreements than by scientific practices. Many national governments wish to assist their companies in developing goods and services for export. Genome projects focused on technology development are likely to be seen in this light. Nationalistic economic policies make projects to develop instruments or other salable goods poor candidates for international cooperation. European nations may be exceptions, because they have a basis for cooperation through several biotechnology programs of the European Economic Community.

Restrictions on international exchange of scientific personnel would disrupt many molecular biology laboratories in the United States and abroad. The United States has often reaped the benefits of international scientific exchange, Senior scientists, postdoctoral fellows, and graduate students from other nations work in U.S. laboratories and attend conferences. In exchange, U.S. scientists visit and are occasionally educated at universities and research centers abroad (12,22). The team of scientists that developed the atomic bomb for the U.S. Army, for example, was heavily dependent on scientists trained in Europe (1.2). Molecular biologists from abroad have often settled in the United States because it is so conducive to scientific research; several Nobel laureates at American universities immigrated during their scientific careers. Many projects in molecular biology have depended heavily on foreign scientists working in the United States, and many of the best stay or eventually return (4). The United States may in fact benefit from international personnel exchanges more than it is hurt by them. The Federal Government could nonetheless limit funding of foreign researchers at U.S. institutions, although this would probably generate ill will and provoke reciprocal actions by other governments.

One of the problems in assessing the potential impact of policies to reduce funding of foreign researchers in American laboratories is the absence of information about their research careers. If most foreign researchers remain in the United States or are particularly productive investigators while receiving Federal funds, then policies to restrict their ingress would be counterproductive.

Extending current restrictions or use of Federal funds for American researchers to travel abroad would be even less politically acceptable and more difficult to implement. It would result in direct loss of information to the United States, because persons traveling abroad are as likely to import information from their foreign collaborators as to export it. Policies designed to inhibit the exchange of personnel, materials, and information across national borders threaten benefits but gain little for the United States.

Promoting domestic exploitation and foreign patenting of new technologies is a more positive

and less politically troublesome means to the same end of improving U.S. economic competitiveness. Such policies can preserve the U.S. lead in research without provoking retaliation or tarnishing the country's prestige.

National Prestige

One argument for Federal sponsorship for genome projects is that they are highly conspicuous and beneficial: Other nations will do the work if the United States does not, to the detriment of US. prestige. Similar arguments have been proffered for the supersonic transport, space programs, and other technical projects. These arguments tie the stature of U.S. science and technology to leadership of genome projects. The international prestige attached to genome projects is a purely political judgment; it cannot be assessed technically.

What would be the consequences if Japan or a European nation were to have the first complete set of ordered DNA clones representing all human chromosomes, or the first reference sequence of the human genome? Such questions are best answered primarily by the scientific and technical merits of the projects, not by an appeal to a vague notion of national prestige. If projects are technically unsound or uneconomical, then the United States would not benefit from a commitment to them. Other countries could do so, but they would only be hurting themselves. If the projects are technically sound, then the United States would do well to lead or at least participate in them, but national prestige would not be the principal justification for involvement. National prestige is not a useful basis for judging major scientific or technical projects.

Military Applications

Military applications of results of genome projects should not prove to be a major consideration in technology transfer. U.S. policies ban the export of goods and technologies that could be used for military purposes by specified hostile countries. Such policies are administered by the Department of Commerce in consultation with the Department of Defense and the Department of State. The export of some goods produced using biological technologies could be affected (1), At present, however, DNA mapping, sequencing, and other means of analysis relevant to genome projects are not on the list of controlled technologies, and this should remain true for the foreseeable future (2). The main reason is that the technologies and data resulting from genome projects would not have immediate military applications. Like other technologies and data, some could conceivably be used for a military purpose, such as devising vaccines against biological warfare agents, but genome projects would not in themselves promote biological warfare.

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