INTELLECTUAL PROPERTY PROTECTION AND GENOME RESEARCH:

BACKGROUND INFORMATION FOR A PUBLIC MEETING

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GENOME PATENT WORKING GROUP

COMMITTEE ON LIFE SCIENCES AND HEALTH

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I. INTRODUCTION

Various federal agencies have established coordinated genome research projects.¹ The National Institutes of Health (NIH) and the Department of Energy (DOE) have established human genome research programs, involving research on genomes of humans and selected model organisms.² The U.S. Department of Agriculture (USDA) supports the plant genome research project³ as well as the animal genome research project.⁴ The National Science Foundation (NSF) supports a genome research project on a model plant system, *Arabidopsis*.⁵ Other countries in Europe and elsewhere have launched coordinated genome projects addressing genomes of humans, plants, animals, and bacteria.⁶

Infusion of new federal funding through these projects into the already strong biological research base in the United States has encouraged genome research in this country and contributed to a rapid rate of scientific progress beyond earlier expectations. For example, new technologies allow for the rapid, and relatively inexpensive, isolation, cloning, and DNA sequencing of genes or gene fragments. Consequently, it is possible to obtain sequences representing a large number of genes for which, in some instances, little other information is available. The Federal Government has a dual responsibility to encourage the free flow of scientific information and the rapid commercialization of research results. In order to address how best to achieve these goals with respect to

¹ A genome is the total gene complement of a set of chromosomes found in higher life forms, or the functionally similar but simpler linear arrangements found in bacteria and viruses.

² Understanding Our Genetic Inheritance. The U.S. Human Genome Project: The First Five Years, FY1991-1995. A joint publication of the Department of Energy and the Department of Health and Human Services. Washington, DC, April 1990.

³ USDA Plant Genome Research Program. Washington, DC: U.S. Department of Agriculture, June 1991.

⁴ Federal Register, Vol. 56, No. 231, 2 December 1991.

⁵ A Long-range Plan for the Multinational Coordinated <u>Arabidopsis thaliana</u> Genome Research Project. Washington, DC: National Science Foundation, July 1990.

⁶ Human Genome Research: A Review of European and International Contributions. London: Medical Research Council of the United Kingdom, January 1991. genome research, the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) has formed a high level interagency committee, the Genome Patent Working Group (GPWG), under the auspices of the FCCSET Committee on Life Sciences and Health (CLSH).⁷ The GPWG is charged with defining the pertinent science and related issues, examining different views and perspectives on these issues, and proposing a series of options to be considered at the policy making level. The scope of the GPWG is limited to the issues related to federally funded genome research.

It should be recognized that rapid progress in genome research is possible only because of the vast accumulated information in biology that has resulted from basic research supported by various agencies over a long period. All the agencies involved in genome research are aware of the importance of integrating genome research with all of biology, as evidenced by the fact that most of the coordinated genome research projects take a broad view of the kind of research and experimental systems that they support. Similarly, issues related to the protection of intellectual property rights and commercialization of federally funded research results are not new or unique to genome research. There are existing laws and policies that deal with these issues. However, genome research has highlighted some of the problems of interpretation and application of existing laws in the rapidly evolving area of molecular genetics.

The GPWG seeks input from many sources in completing its tasks. The purpose of this document is to provide the interested public with general information on what genome research is, how intellectual property is protected, and how the Federal Government encourages technology transfer from laboratories to commercialization. The document is written as background for a public meeting to be held on May 21-22, 1992, in Washington, D.C. It is not designed to be a comprehensive treatise, but is intended rather as an aid to focus the discussion about this extremely complex subject on a few key issues of common interest. Examples of these issues are identified in Section VI at the end of this document.

II. SCIENTIFIC BACKGROUND

<u>Genome Projects</u>. Since the discovery of the double helical structure of deoxyribonucleic acid (DNA) by Watson and Crick in 1953, it has been evident that the sequence of its "letters" (the nucleotide bases adenine, cytosine, guanine, and thymine--or A, C, G, and T, for short) was the key to its information content. The Human Genome Project, cosponsored by the DOE and the NIH, is a coordinated 15-year effort to locate and

⁷The seven member agencies are the Departments of Agriculture (USDA), Commerce (DOC), Energy (DOE), Health and Human Services (DHHS), and State (DOS), along with the National Science Foundation (NSF) and the Office of Science and Technology Policy (OSTP). The NSF chairs the working group.

decode all the information in the complete human DNA, or human genome. Concurrently with the development and establishment of the Human Genome Project, the USDA planned and established the Plant Genome Project in 1991. The goal of the USDA project is to facilitate the genetic improvement of plants by locating important genes and markers on plant chromosomes, determining the structure of those genes, and transferring the genes to improve the performance of commercial plant varieties to meet market needs.

The genome exists in living cells in highly organized structures called chromosomes. The number of chromosomes varies greatly from species to species, but is always a characteristic number for each species. In the case of humans, each of the 24 distinct human chromosomes is a single, enormously long, double helical molecule (averaging an inch and a quarter per chromosome, with 23 pairs of chromosomes stuffed into a volume of less than one billionth of a cubic centimeter within each nucleated cell). Along the length of that molecule are regions of special sequences, called genes, that are functionally distinct because they encode instructions for the manufacture and control of products (proteins) that build, manage, and organize everything in the cell--which is itself the basic building block of all living tissues. It is estimated that an adult human being has about one hundred trillion (100,000,000,000,000) cells of many different kinds and functions. To oversee this complexity, the organization of the information contained in the genome must also be highly complex so that only the genes needed to do specific jobs are expressed where and when necessary. The genomes of some crop plants can be even more complex, with multiple copies of chromosomes beyond the normal number of two of each. The need to understand the basic structure and organization of the genome--whether human, animal, or plant--is a driving force behind the several organized genome projects.

The Human Genome Project departs from the norm for basic biological research in several ways: it is a focussed and technology-dependent, basic research effort, and it is a highly interdisciplinary project. Its principal objective is a delineation of all three kinds of maps of the human chromosomes - genetic, physical, and DNA sequence. Accomplishing this daunting task will require further technological advances, instrumentation, and chemistries that will permit us to analyze the fundamental molecules of life, DNA and proteins, as well as to develop the sophisticated new computational methods needed to interpret the information.

<u>Research Objectives</u>. In the past, research investigating the causes of genetic diseases in humans and animals, or genetic defects in plants and microorganisms, focused on identifying the missing or defective protein associated with the symptoms of such illnesses or defects. The vast improvements in technology over the last two decades have made it possible to examine the genome at the molecular level, to pinpoint the precise location of the defects within the protein sequence and to place the location of the gene coding for that protein on a genetic map. Such information is equally valuable for understanding normal cell function and physiology. Today, research is conducted from both directions, from the gene to the protein and the protein back to the gene. In either case, each step in the process of DNA transcription and RNA translation into proteins provides vital insight into the sophisticated means for controlling gene expression, cell development and organismal function.

Scientists do not yet thoroughly understand the organization of the information in the genome of even a very simple organism--much less the human genome; nor do they understand all the multiple and subtle control mechanisms that operate within the genome. Current estimates are that there are perhaps 100,000 genes in the human genome, of which, to date, some 5,000 are named and 2,300 localized (mapped) onto one of the 24 distinct chromosomes. For fewer than 1,500 human genes is there even a partial understanding of their function. The first step in building this understanding is to construct a detailed "map" of where the genes are. There are several different kinds of map, of different levels of resolution, that are obtained using different technologies. One of the aims of the Human Genome Project (and other genome projects) is to place reference points, or landmarks, on the chromosomes so that genes can be located as they are found. This procedure is similar in concept to the mile markers on interstate highways. The marker may not, by itself, indicate anything more than the number of miles from a state line (by convention, either the south or west border), but it is very useful as a milestone to someone traveling on the highway. The most useful markers have two qualities: (1) they must be easily recognizable and (2) there must be lots of them, spread relatively evenly along the length of the chromosome so that one is never. very far away from a unique point. The Human Genome Project has recently seen the mapping of almost 1,000 specific sequence markers (referred to as Sequence Tagged Sites, or STSs). An STS is a short stretch of consecutive DNA sequence that is usually not enough to code for a full protein, or to deduce anything about the function of the protein for which the STS serves as a marker. However, it is by definition unique, i.e., nowhere else in the entire genome will the same sequence be found. These STS markers represent only a small percentage (about 3.5%) of the number that will be needed to complete the map for the human genome at the prescribed resolution.

Another approach to mapping uses a special construct called cDNA (for "complementary DNA"). In the cell, the DNA constituting a gene is first transcribed into a temporary intermediate molecule, and then processed through the precise removal of intervening sequence fragments into an edited form of RNA called mRNA (for "messenger RNA") that codes for a specific protein. Using recombinant DNA techniques, it is possible to synthesize and clone a complementary strand of DNA using the mRNA as a template. Once it is cloned, or purified and multiplied in culture, this cDNA can be used to isolate the corresponding gene from a large mixture of such sequences. With automated technologies, it is now possible to rapidly sequence portions of a large number of these cDNAs. Partial cDNA sequences have been referred to as "expressed sequence tags" (ESTs) because they identify expressed genes. Since this working copy bears sequence information that may be unique to the protein product, its sequence can be useful for

identifying on the original starting chromosome exactly where the gene for the given protein is situated, thus mapping it.

Intensive efforts are currently under way in the United States and many other countries around the world to continue and accelerate mapping efforts, both in humans and in selected model organisms. The ultimate map will be the complete nucleotide sequence of the genome.

Potential Benefits of Genome Research. Many genes code for the production of protein products; these proteins are used to build other proteins, to assemble the physical structure of a cell or tissue, and to serve as enzymes (which carry out the metabolic reactions) or as signal molecules (hormones, needed for internal regulation and control) that are necessary for the functions of a cell and ultimately of the organism. Human diseases can result when there is an error in the gene coding for a protein product that catalyzes necessary cellular chemical reactions. One example is cystic fibrosis, in which a very small change in the gene sequence results in a defective membrane transport molecule that cannot efficiently control the flow of chloride ions into certain cells. As a consequence, these cells improperly regulate the amount of water kept inside the membrane and they retain more than they should. This results in the formation of a sticky mucous secretion which is characteristic of the disease and is the source of the clinical symptoms, particularly in the lungs and pancreas. In another example in plants, a single base pair change in the gene sequence that encodes a chloroplast membrane protein can result in herbicide resistance.

The identification of genes offers several kinds of promise. The product of the gene can be manufactured using recombinant DNA methods and this product supplied as a drug or other useful compound for humans, animals, and plants. The gene itself can be supplied using gene therapy approaches. In addition, specific genes can be used to modify or genetically engineer plants, animals or microbes. These prospects offer opportunities for commercial benefit to the inventors and developers of such products and therapies. As more human genetic defects are identified, many new and extremely specific therapies and medicines will emerge for diseases that have few effective therapies today. Similarly, as more economically important genes are identified in crop plants, many new varieties will emerge that could help increase efficiency and reduce losses in crop production. For humans, as well as for plants and other organisms, the elucidation of the organization and function of the genetic endowment will ultimately lead to enormous utility and benefit.

III. INTELLECTUAL PROPERTY PROTECTION

<u>The Patent System</u>. The U.S. Constitution, through Article I, Section 8, clause 8, has empowered Congress with a broad grant of authority to promote the "Progress of Science and the Useful Arts." The basic concept of the patent system is that providing a limited

grant of exclusive rights to inventors will give them an incentive to disclose their inventions to the public, rather than retain them in secrecy. Through this mechanism the public gains information not only on technical advances, but also on activities of their competitors in related fields of technology, so as to prevent duplicative research efforts. The incentive offered is a 17-year grant of a right to exclude others from making, using, or selling the invention. The patent grant does not, however, provide the patent holder with authority to make, use, or sell the patented invention; it only provides authority to preclude others from such activities. Thus, for example, if a person obtains patent protection for an improvement to a basic invention patented by another, that patentee may not be able to commercially exploit the improvement unless permission from the owner of the basic patent is obtained. The improvement patent will, however, enable the patent owner to preclude all others, including the basic patent owner, from making, using or selling the improvement.

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<u>Basic Requirements for Patentability</u>. There are four fundamental, statutory requirements that every invention must meet in order to become entitled to patent protection, regardless of the technological field of the invention: utility, adequacy of disclosure, novelty, and non-obviousness.

First, the patent applicant must demonstrate that the invention is "useful" in a practical sense. This requirement, referred to as utility (35 U.S.C. 101), is met when the patent applicant identifies some useful purpose to which the invention can be applied. In addition, some discoveries which are unapplied mathematical algorithms, laws of nature, abstract ideas, or natural products indistinguishable from the form in which they exist in nature are not protectable through the patent laws. Note that practical utility in its patent law sense may be entirely different from biological or therapeutic utility.

Second, to obtain a patent for a new invention, one must file an application that describes the invention in detail and describes the subject matter for which patent protection is sought. Each patent application thus has two sections, the specification and the claims. The specification describes in detail the field of technology to which the invention pertains, and then describes, both generally and in detail, the features of the invention. The claims, on the other hand, set forth in detail the subject matter for which the patent applicant desires protection.

Substantive application disclosure requirements are governed by 35 U.S.C. 112. This section of the patent code requires that applicants describe their invention in sufficient detail as to enable a person skilled in the field of technology to which the invention pertains to "practice" the invention. Hence, many patents on inventions involving biological material require deposit of a specimen. This requirement ensures that patent documents include a sufficient technical description of the invention to people working in the field of the invention, so as to provide them with the opportunity to study and to improve upon the patented invention.

Novelty refers to the requirement that the invention not be known or in use prior to the filing of the patent application. A lack of novelty, which will preclude the grant of a patent, can be based upon any prior publication, an issued U.S. or foreign patent, or evidence that the invention was in public use or was on sale more than one year prior to the filing of the application. An absolute bar to patentability due to lack of novelty can occur if there was prior disclosure, use, or sale more than one year before the filing of the U.S. patent application. Where the publication or use occurs less than one year prior to the application filing date, the patent applicant may still be able to overcome the novelty bar and obtain a patent. However, this one year "grace period" does not apply in most foreign countries. Thus, publication or use without the prior filing of a patent application could eliminate the possibility of obtaining patent protection in major international product markets.

The final requirement for patentability is that the invention be non-obvious as stated in 35 U.S.C. 103. This requirement serves to preclude patenting of minor improvements, where those improvements would have been considered to have been obvious to a person skilled in the field of the invention. Measuring whether an invention would have been obvious requires an assessment of several factors, including the state of the art at the time the patent application was filed, the level of skill of the ordinary worker in the field of the invention, and the difference between what the applicant has claimed as his or her invention, and that which is known in the prior art. (The term "prior art" refers to patents, technical publications, and other published documents available anywhere in the world prior to the filing date of a particular patent application and evidence of public use or sale in the United States.) Additional factors, such as an invention's immediate and widespread adoption, the commercial success of the invention, or proof that the invention solved a long-felt need, may be offered to establish that the relevant prior art does not render the invention obvious.

<u>Patent Examination Process</u>. The U.S. Patent and Trademark Office (PTO) receives a tremendous volume of patent applications from inventors both in the United States and abroad. For example, the Office received over 165,000 applications in 1991. To ensure rapid examination of patent applications, the PTO employs more than 1,800 examiners who examine applications involving virtually every imaginable field of technology. In the field of biotechnology, the PTO employs over 150 highly skilled scientists, most of whom have advanced degrees and/or postdoctoral experience. Despite the volume of applications, the PTO has maintained an average pendency for filed applications of less than 19 months between the date a patent application is filed, and the date of its final disposition by the PTO.

Each patent application undergoes a rigorous examination to ensure that it satisfies the statutory requirements of the patent laws, as well as the formal requirements of the PTO. During the examination process, patent applications are kept confidential - patent examiners and PTO staff are prohibited by law from disclosing the content of pending applications. If the examiner in charge of prosecution of a patent application determines

that the application satisfies the formal and statutory requirements of patentability, the PTO will issue the application as a patent. This will result in the application being printed and made available to the public.

If an examiner determines that a patent application does not satisfy the criteria for patentability noted earlier, the patent application will be rejected. If the decision of the examiner is made final, the patent applicant can appeal to the Board of Patent Appeals and Interferences, an appellate panel within the structure of the PTO staffed by experienced examiners who are also lawyers. If the Board upholds the rejection, the applicant may seek judicial review of this decision, and may ultimately petition for *certiorari* to the Supreme Court.

<u>Plant Patents</u>. In addition to utility patents, plants are afforded two other forms of protection. Title 35 of the U.S. Code, section 161, provides protection for asexually reproduced varieties of plants, including cultivated sports, mutants, hybrids and newly found propagated plants, but excludes tuber-propagated plants or plants found in an uncultivated state. The Plant Variety Protection Act (PVPA) of 1970 provides patent-like protection for sexually reproduced varieties of plants excluding fungi, bacteria, or first generation hybrids. The PVPA was initially enacted to bring the United States into compliance with the International Convention for the Protection of New Varieties of Plants (UPOV). Recently, this Convention has been revised to extend protection for the developer of a new variety to include related varieties "essentially derived" from it.

The PVPA also contains a provision that provides a research exemption. Section 114 of the PVPA defines this exemption as follows:

The use and reproduction of a protected variety for plant breeding or other *bona fide* research shall not constitute an infringement of the protection provided under this Act. (7 U.S.C. 2544).

Since any distinct, uniform, and stable variety developed in such research would in turn be eligible for a Plant Variety Protection certificate, it follows that such a variety derived directly from a protected one would itself also be protectable.

<u>Enforcement of Patent Rights</u>. As noted above, a patent gives its owner the right to preclude others from making, selling, or using the invention described in the claims of the patent within the territorial limits of the United States. This right is classified as a property right, and can be assigned to others or licensed on an exclusive or non-exclusive basis. To enforce one's rights under a patent, one may file a civil suit in a Federal District court, alleging patent infringement. If successful, the patent owner may obtain an injunction, monetary damages, or both. Thus, the patent owner can effectively stop the patent infringer from making, using, or selling the patented invention, and may recoup whatever damages were incurred during the period of infringement. Experimental Use Defense. A limited defense may be available to a party charged with patent infringement if the use of the patented invention was for academic, noncommercial research purposes. This defense, termed the experimental use defense, developed and continues to be largely governed by case law. It is important to note the defense is rarely invoked, and will not be effective if the use of the patented invention was to discover a means of exploiting the patented invention commercially. In addition to the common law experimental use doctrine, the patent law provides an explicit exemption from infringement for parties other than the patent owner who make, use, or sell patented drugs where the use is solely for the purpose of producing data to satisfy requirements for federal regulatory review (e.g., FDA marketing approval).

Foreign Patent Systems. Patent systems outside the United States share many substantive similarities with our system. For example, most industrialized nations with patent systems require the elements of utility, adequate disclosure, novelty, and nonobviousness, irrespective of the names which are used to describe these elements. The primary differences lie in the procedural elements of our system. Thus, in every country except the United States and the Philippines, if a conflict in priority arises over which of two inventors of the same invention is entitled to a patent, the patent is awarded to the first party to file the patent application. In the United States, the patent is granted to the first inventor.

Another significant difference between the U.S. and foreign systems is the absence of a "grace period" in foreign systems. The grace period provides inventors with up to one year to file patent applications after publication of the invention. Thus, a patent applicant in the United States can overcome a rejection based on prior art if the publication relied upon to defeat novelty was authored by the inventor and published less than one year before the date of filing of the patent application. In most foreign systems, the novelty bar could not be overcome even if the publication was by the same inventor.

One mitigating factor against harsh results of the lack of a grace period is the right of foreign priority provided through the Paris convention. This convention is a treaty which has been signed by over 100 different countries. Through the treaty, an individual can file first in the United States, and then for up to one year file abroad in treaty countries. The priority right allows the applicant in his/her foreign application to rely upon the date of filing in the United States. This is also true for applications filed in foreign countries and then filed in the United States.

<u>Biotechnology</u>. In recent years, biotechnology has brought an avalanche of new patents. These range from the genetically engineered Harvard mouse to a tasty tomato with extended shelf life, to a recombinant bacterium (E. coli) that can convert a whole spectrum of sugar molecules into ethanol. The avalanche in patent application filings was unleashed by the 1980 holding of the Supreme Court in <u>Diamond v. Chakrabarty</u>

that a bacterium altered through genetic engineering techniques that was different from the bacterium as it existed naturally was eligible for patent protection.

<u>Copyrights, Trademarks, and Trade Secrets</u>. Other forms of intellectual property protection include copyright, trademark, and trade secret protection. Of the three, only trade secret protection has no federal component. Though copyrights were originally envisioned to cover the discoveries of the genome projects, that idea was quickly abandoned because copyrights do not protect an idea but only the expression of the idea and do not extend to any procedure, process, system, method of operation, concept, principle, or discovery. Trademarks have no applicability in protecting genome discoveries.

A trade secret is the term used to describe proprietary information or materials that are kept in confidence and have value to their owner only to the extent that they remain secret. For example, the formula for Coca-Cola is one of the classic examples of a trade secret. Trade secrecy is used in private industry either to provide a competitive business advantage, or prior to the time the invention has matured to the point where it is ripe for the patent process. Trade secrets are governed by state law, most of which are patterned after the Uniform Trade Secrets Act. Trade secrets rights cannot be held and enforced by the Federal Government. Thus, except for information whose disclosure is restricted through federal laws or regulations, any citizen can compel disclosure of information generated by a federal laboratory or agency through the Freedom of Information Act. An important exception to this policy of disclosure is created by the National Competitiveness Technology Transfer Act, which authorizes laboratories to withhold from disclosure certain categories of information relating to Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 (FTTA) for up to five years.

<u>Dedication to the Public</u>. Another option under some circumstances is dedication to the public. This is the deliberate destruction of an invention's patentability by disclosing it through publication, public use, or a Statutory Invention Registration. (A Statutory Invention Registration, or SIR, is issued by the Patent and Trademark Office. An application for a SIR must disclose the same information about an invention that a patent application would, but need not meet the requirement of novelty, non-obviousness and utility. As a result, a SIR can be issued much faster than a patent.) To be effective, a disclosure must describe the invention. If someone has already filed a patent application — or, under the U.S. "grace period", someone files within one year after the "dedication": and can show that he or she made the invention before it occurred — a valid patent on the invention could still be obtained. Dedication to the public is

appropriate when the exclusive rights to an invention that might be secured through patenting have no commercial value.⁸

IV. LICENSING

<u>Background</u>. The patenting and licensing of inventions made by federal employees as well as the recipients of federal funding is authorized by U.S. patent law and regulations. Congress legislated a preference for patenting when it enacted the Patent and Trademark Act Amendments of 1980.

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development ... to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions ...

For federal research laboratories, the Federal Technology Transfer Act of 1986 (FTTA) further authorizes the sharing of royalty revenues with inventors and the retention of royalties at the agency level for various purposes related to enhancing technology transfer activities. The FTTA strongly encourages agencies to transfer commercially applicable technology through patenting and licensing, although this is not mandatory.

Licensing Process of the Federal Government. The licensing rules applicable to all government inventions are set forth in the patent law at Title 35, United States Code Sections 200-212 and implementing regulations of the Department of Commerce at Volume 37, Code of Federal Regulations, Part 404. Pending patent applications also are routinely licensed by Government as well as industry and academia, although enforceable patent rights do not exist until a patent is actually issued by the U.S. Patent and Trademark Office. Because patents grant limited rights (see Section III), a patent license agreement cannot grant rights to use or sell a product where regulatory approval (e.g., from the FDA) is legally required; the license merely is a promise by a licensor not to sue a licensee for patent infringement.

Typically, the licensing of Government inventions is pursued by the involved federal agencies shortly after the filing of a patent application. Inventions that are available for licensing typically are identified through notices published in the Federal Register to invite the filing of license applications by prospective licensees. If an agency contemplates licensing an invention exclusively, a notice of that intention must also be published in the Federal Register. Applicants for license are required by law to submit

⁸ See, for example, section 650.10, "Unwanted Inventions" of the National Science Foundations" "Patents" regulation, 45 CFR 650.10.

plans for the development and/or marketing of inventions. The application period must be held open for at least 30 days before a subsequent Federal Register notice would be permitted to announce a contemplated exclusive licensee for such inventions. Following the announcement of an agency's intention to license an invention exclusively, a 60-day objection and comment period is mandatory.

The agency handling the licensing of a given invention has the responsibility for promoting their inventions, making judgments as to the appropriate degree of exclusivity to grant in a license, and determining which applicants are qualified and acceptable. Actual license negotiations often focus on business matters, such as royalty rates and benchmarks for assessing the likely diligence of a licensee's performance. Many agencies utilize a model licensing agreement based on agreements developed in academic licensing offices. Licenses normally are granted to companies that agree to manufacture in the United States any inventions that are to be used or sold in the United States, although waivers from this requirement may be obtained in appropriate circumstances. Licensing practices at DOE's Government-owned-contractor-operated (GOCO) laboratories are more like those followed by universities.

<u>Licensing Process in Academia</u>. The negotiation process utilized in academia is very similar to that of Government agencies because the kinds of terms to be negotiated are generally very similar. However, the competitive aspect and public notice requirements that pertain to licensing as described above do not apply to universities. Some universities have their own procedures about selecting licensees, particularly when companies founded by their own faculty pursue license rights. Often, universities promise invention rights to their research sponsors for applicable studies.

Federal law does require that the Government retain a nonexclusive, paid-up license to practice (or have practiced) any invention made with Government funding. This applies whether the invention is made by Government employees or grantees. The domestic production requirement discussed above also applies to licensing by grantees.

<u>Exclusive vs. Nonexclusive Licensing</u>. For the licensing of any given invention, the exclusivity of available rights falls along a continuum ranging from nonexclusive to semiexclusive to exclusive. Government agencies and academic licensing offices have the legal flexibility to provide through licensing the degree of exclusivity needed to facilitate the development of particular products. The paramount consideration in determining the degree of licensing exclusivity is the encouragement of product development. However, obligations to partners in Cooperative Research and Development Agreements (CRADAs) pursuant to the FTTA (at Government agencies) or to research sponsors (at universities) may preempt a more open approach to licensing.

Nonexclusive licensing typically is appropriate for very basic and enabling technology, such as certain types of materials having many different commercial uses or general laboratory techniques. Semi-exclusive licensing, in which a few licensees share patent

rights, becomes appropriate when there are larger markets, lower developmental costs, and less overall risk. Exclusive licensing is appropriate when it is determined that nonexclusive licensing will not lead to expeditious product development.

<u>Issues of Scope.</u> The scope of rights that can be licensed also lies along a continuum for any particular invention. Rights to commercialize all uses may be granted, or more limited rights to a family of diagnostic or therapeutic products might be licensed, or perhaps only the rights to commercialize a specific product for a specific use. Rights may also be divided by geographic territories.

A family of uses itself can be of variable scope and might include, in the case of medical products, for example, all cancer therapeutics or all solid tumor anticancer therapeutics. Decisions about the appropriate scope of rights generally are made after consideration of factual data about various factors, including market size and affected patient population.

<u>Royalty Rates</u>. Royalties also fall along a continuum ranging from no charge in cases where patents effectively are dedicated to the public, to a cost recovery level that would recoup patenting and administrative costs, to market rates. Most Government agencies and universities have adopted a model system for which royalty rates generally fall within a range of about 0.5%-6% of product sales, depending on the extent to which the Government or university scientists have developed a product--i.e., from basic research through some development or prototyping stages--before it is licensed.

<u>Procedural Issues</u>. Various standard licensing provisions and practices may be modified to facilitate the transfer of specific types of inventions. For example, minimum notice provisions can be expanded where extra concern exists about increasing disclosures of licensing opportunities.

V. THE FEDERAL TECHNOLOGY TRANSFER LAWS AND THEIR IMPLEMENTATION AT VARIOUS FEDERAL AGENCIES

<u>Mechanisms for Technology Transfer</u>. The Stevenson-Wydler Technology Transfer Act (15 U.S.C. Section 3701-14), as amended by the Federal Technology Transfer Act of 1986 and the National Competitiveness Technology Transfer Act of 1989, directs the Federal Government to transfer federally owned or originated technology to State and local governments and to the private sector, where appropriate. The Act, which affects only federally owned laboratories (Government-owned-contractor-operated and Government-owned-government-operated facilities), authorizes a variety of mechanisms designed to promote the transfer of technology to the marketplace, including Cooperative Research and Development Agreements (CRADAs) between federal labs and non-federal entities; award programs for federal employee-inventors; and royalty sharing with employee-inventors when agencies retain ownership of the inventions. It

also directs agencies to allow their employees to patent inventions when the agencies do not themselves patent or "otherwise promote commercialization" of those inventions.

The Stevenson-Wydler Act prescribes certain technology transfer activities requiring Offices of Research and Technology Applications at each federal laboratory over a certain size and establishing the Federal Laboratory Consortium for Technology Transfer. Nevertheless, technology transfer activities do vary from agency to agency because of differing structures and missions.

<u>Agency Activities</u>. The Department of Agriculture has a long history of developing farmrelated technology and disseminating it to farmers, and its Agricultural Research and Forest Services have entered into about 250 CRADAs since the Federal Technology Transfer Act became law.

The Department of Commerce, through its National Institute of Standards and Technology, regional Centers for the Transfer of Manufacturing Technology, and Advanced Technology Program, carries out cooperative programs with industry in order to speed innovation and accelerate the adoption of new technologies by U.S. companies. It also sponsors conferences and seminars focusing on government-university-industry partnerships and enters into CRADAs with private industry.

The Department of Energy, whose laboratories are operated by contractors in most cases and by DOE in others, aggressively pursues and encourages technology transfer. Each DOE laboratory has a Technology Transfer Office, and under authority provided in the NCTTA, DOE uses CRADAs and other collaborative agreements to transfer technology to the marketplace. In addition, DOE and DOE supported laboratories sponsor conferences and seminars, and license technologies.

The Department of Health and Human Services, through the National Institutes of Health, operates the world's largest biomedical research facility. It transfers all types of biomedical and health-related research to the scientific community and to industry through the publication of articles in scientific journals and the sharing of research materials, as well as through licensing agreements and CRADAs. The NIH Office of Technology Transfer's licensing efforts include: promotion of technologies at conferences and meetings; publication of an annual directory on technology transfer at NIH; an online abstract of Public Health Service (PHS) technologies; and a database of companies and their interest by technological field for direct marketing of PHS technologies to industry.

Since the National Science Foundation is barred by its Organic Act from itself operating any laboratories and the federally funded research and development centers it owns are chiefly astronomical observatories, most NSF-originated technology comes from non-Government-owned laboratories, largely at colleges and universities. Like most federal agencies, the NSF allows its contractors and grantees to retain the principal rights to inventions and other forms of intellectual property produced through NSF-funded research. This treatment of inventions is required in awards to small businesses and non-profit organizations, including universities, by the Bayh-Dole Act. A Presidential Memorandum issued in 1983 directs agencies to apply the policies of that Act to all awardees unless prevented from doing so by statute. Policies directing agencies to leave with the grantees the rights to software, data, and other copyrightable material are stated in the Office of Management and Budget circulars and the Federal Acquisition Regulations. Allowing commercial rights to remain with the institutions or individuals that performed the research assures that those with the greatest knowledge of the technology have the maximum incentives to bring it into the marketplace.

VI. ISSUES AND QUESTIONS

As is often the case with any rapidly advancing field of science, genome research has drawn (and will continue to draw) many new participants unfamiliar with pertinent laws and practices; and it has produced (and will continue to produce) scientific discoveries that do not fit neatly into existing molds. This document, in Sections II-V, provides a baseline of information about the existing means of protection of intellectual property and current technology transfer practices. An understanding of these issues will form the background for the public meeting to be held on May 21-22, 1992, in Washington, D.C. The purpose of the public meeting is to involve all interested parties in identifying science and technology transfer issues central to maintaining scientific advances in genome research and promoting rapid application of new discoveries to commercial development. In order to facilitate discussion at the public meeting, the GPWG has identified some key issues and questions, as listed below.

A. <u>Genome Research</u>

- What impact, if any, would the Federal Government's use of the existing system for the protection of intellectual property have on Federally funded genome research, given applicable exemptions from infringement liability for noncommercial academic research (see Section III)?
- What, if any, consequences for scientific progress would result from the Federal Government holding patents on key products of genome research? Would any adverse consequences be ameliorated if Federal agencies adopted licensing policies (e.g., nonexclusivity, limited scope, low royalties) for use of such patents by researchers?

How would the impact of Government ownership of intellectual property rights on Federally funded research differ depending on the level of research (e.g., basic

research as compared to applied/development research); and depending on the recipient (e.g., Government laboratory, grantee or contractor)?

How would the impact of Government-owned intellectual property rights on Federally funded research differ depending on the genome being studied (e.g., human, farm animal, crop plants, or industrial microorganisms); depending on the stage of research (e.g. extent of knowledge about the biological function of gene sequences); and depending on the anticipated products of the research (e.g., molecules or whole organisms)?

B. Commercialization of the Products of Federally Funded Genome Research

Should the policies which govern the ability of participants of Federally funded research to seek patent protection on genome research be changed? Are there any important circumstances that make Federally funded genome research different from other Federally funded biological research? If so, what are those special circumstances and what impact would they have on the application of Federal laws and policies relating to the transfer of Federally funded technologies to the private sector?

To what extent might publication, patents (if granted), licensing, and other forms of dissemination of the results of genome research at an early stage of discovery, (e.g., gene sequences for which the biological functions are not yet determined), provide incentives or disincentives to product development?

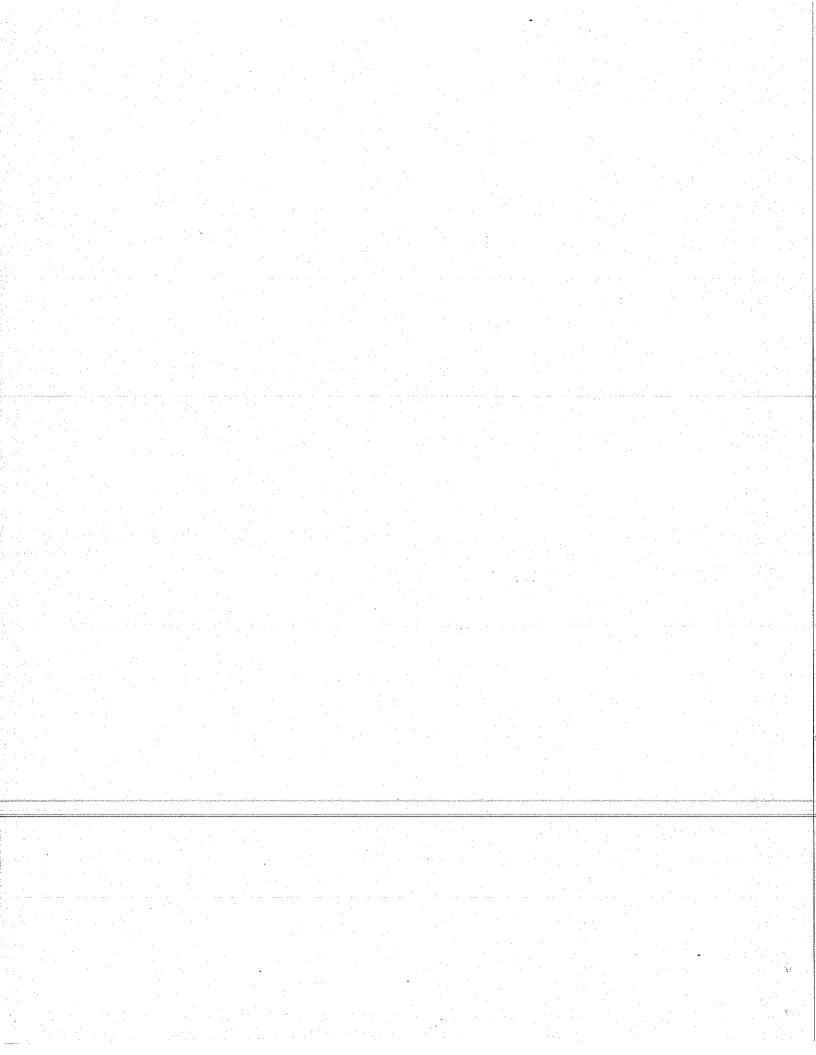
Following publication of sequence data would sufficient intellectual property protection be available to stimulate product development?

- What effect, if any, would result from the U.S. Federal Government owning patents on DNA sequences, in contrast to ownership by the private sector, foreign and domestic, on the public interest (e.g., the rapid introduction of new, safe and effective products at reasonable prices?)
- What impact, if any, will ownership and use of intellectual property rights covering inventions arising from genome research by the United States or foreign governments have upon the willingness of U.S. companies to develop specific products based upon or derived from such research?
 - Should patenting, licensing and technology transfer policies be uniform for all recipients of Federal funding, whether they are Federal laboratories, contractors or grantees?

C. <u>Collaboration</u>

What impact, if any, might the Federal Government's use of the intellectual property protection system have on data and resource sharing both nationally and internationally?

- What impact, if any, might the decision of the U.S. Government to seek patent protection for gene sequences have on genome research partners and practices in other countries?
- How can both dissemination of research results and the encouragement of product development be facilitated on an international scale?



NEXT

Four Years of Reagan Science Policy: Notable Shifts in Priorities

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G. A. Keyworth, II

Four Years of Reagan Science Policy: Notable Shifts in Priorities

G. A. Keyworth, II

The presentation in February 1984 of the President's proposed programs for research and development in fiscal year 1985 marked the fourth R & D budget of the Reagan Administration. From its early days, the Administration had repeatedly stated its intention to develop and implement a new science and technology policy, one developed not so much in response to the needs of the science community as in response to the broader needs of the nation. It also stated its intention to reorder the priorities among the kinds of R & D funded by the government, more clearly delineating the responsibilities of government and the private sector.

Perhaps the most important element of policy that emerged from those reassessments was a renewed—and considerably strengthened—commitment to federal support for basic research. Not only is basic research an essential investment in the nation's long-term welfare, but it is largely a federal responsibility because its benefits are so broadly distributed. Quite simply, basic research is a vital underpinning for our national well-being. There are three reasons for that.

Importance of Basic Research

First, research grants to universities, where the majority of the basic research is done, permit the training of tens of thousands of graduate students under some of the most demanding and stimulating research conditions anywhere. This new talent will be responsible for maintaining American technological leadership in coming years. Second. strong support for basic research permits U.S. scientists and engineers to challenge intellectual frontiers in the most important fields of science and technology. That provides the new knowledge that drives our economic growth. improves our quality of life. and underlies our national defense.

Funding Trends

The Office of Science and Technology Policy has assembled funding data that include the most recent budget proposals and which are corrected for inflation so that they reveal true purchasing power of R & D funds. The overall trend of nondefense federal R & D obligations (Fig. 1) clearly shows, for the period of 4 years, a strong emphasis on basic research as well as a concomitant reduction of government support for demonstration, development, and applied research projects that are considered to be more appropriate for the private sector. This is consistent with the Administration's stated objective of clarifying public and private sector responsibilities for funding R & D. In particular, substantial reductions were made in energy-related demonstration projects.

The result is that among the three

Summary. Administration priorities for federal support of nondefense research and development emphasize basic research and the concomitant training of students. In 4 years basic research has moved from the smallest to the largest component in nondefense R & D expenditures, and basic research specifically to universities has grown by 26 percent in real terms during that period. New programs for fiscal year 1985 emphasize engineering education and research, as well as improved interactions between universities, federal laboratories, and industry.

And third, well-chosen basic research projects can stimulate productive partnerships between scientists and engineers in all sectors of society—partnerships that are increasingly vital to development of new technologies that will keep American industry competitive with improving foreign industries and will speed the application of new knowledge to our increasingly technological defense needs.

What, then, does the 4-year record of R & D programs show? How successful has the Administration been in carrying out its stated objectives, and what have been the implications for science and technology in the United States?

It is possible to get a general answer to the first part of that question by looking at the way in which the Administration allocated R & D resources during those 4 years—and the way the allocations differ from previous patterns.

categories of federal funding-basic research, applied research, and development-there has been a marked shift in relative priorities over a relatively short period of time. Basic research has gone from the smallest fraction of nondefense R & D to the largest, with a jump in share from 27 to 38 percent. At the same time, development funding has dropped from a 42 percent share to 27 percent. (Data in Fig. 1 focus on nondefense R & D. Unlike other areas of technology, the government is the sole customer of defense-related R & D: development costs cannot be shifted to the private sector.)

A look at basic research obligations (Fig. 2) shows that federal support for

The author is science advisor to the President and director of the Office of Science and Technology Policy, Executive Office of the President, Washington, D.C. 20506. This article is adapted from the texof his remarks for the annual AAAS R & D Polic-Colloquium, 29 March 1984. basic research for the five largest R & D funding agencies has grown since 1978 (in constant dollars). All five agencies the National Institutes of Health, the National Science Foundation (NSF), the Department of Energy (DOE), the Department of Defense (DOD), and the National Aeronautics and Space Administration—demonstrate strong and consistent growth in basic research obligations, and in four instances that growth follows level or even declining real budgets in the 4 years preceding 1982:

Figure 3 illustrates how the increases in basic research are affecting universities and colleges. Here the result of the science policy is even more pronounced. Although it is not shown, we could trace a consistent decline in basic research funding for universities back to 1968, and where the data pick up we see that there was essentially no growth from 1979 to 1981. However, from the fiscal 1981 budget to that proposed for 1985, this support for universities grows by 26 percent-again, in real terms. The full impacts of these increases have not yet been felt on the campuses because the actual appropriations lag considerably behind the fiscal year budget proposals. For the most part we are only now beginning to feel the effects of the steeper parts of those curves.

Moreover, the true impacts on universities of federal funding are even greater because so much university research draws on federal investment in special centralized facilities. Substantial amounts of the funds that go to federal and national laboratories actually support university-research-in-physics-astronomy-materials sciences, and space sciences. Thus, as I have been pointing out for as long as I have been in Washington, during the Reagan Administration we have seen the strongest support for basic research in 20 years.

Some highlights of the President's proposed fiscal year 1985 R & D budget are shown in Table 1. Total federal R & D will amount to \$53 billion, an increase of 14 percent from 1984. During the 4 years of the Reagan Administration federal funds for R & D have increased by 52 percent. The largest increases for next year, 22 percent, will be for defense R & D, with the next largest component going to basic research. Since 1981 basic research has grown by 55 percent to a new high of \$7.9 billion. More than half of that support will go to universities.

As in previous years, we are applying the increases in basic research funds selectively to fields and projects showing strong opportunity and excitement, with high priority continuing to go to support

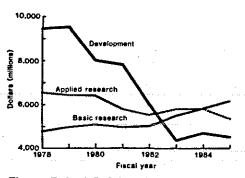


Fig. 1. Federal R & D obligations (nondefense) in constant 1983 dollars. [Source: Office of Science and Technology Policy (from Special Analysis K: Research and Development, the Budget of the United States Government. Office of Management and Budget. Washington, D.C., February 1984)]

university research. This kind of support is the most important element of the budget in continuing on the path to restoring the health and vitality of our nation's universities.

As I have mentioned, there are three broad goals embodied in our programs for science and technology. These relate to ensuring the continuing supply of bright new technical talent to meet national needs, to selecting the most important and most relevant fields of R & D to pursue and then pursuing them as well as we possibly can, and to stimulating new and productive partnerships that span the range of people and organizations conducting R & D.

To help explain the kinds of specific activities that we are proposing to achieve those goals. I want to describe just a few of the initiatives proposed in fiscal year 1985. Each illustrates our determination to retain U.S. scientific and technical leadership in the fields that we believe are most important.

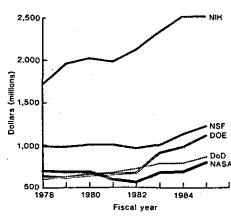


Fig. 2. Basic research obligations in constant 1983 dollars. [Source: Office of Science and Technology Policy (from Special Analysis K: Research and Development, the Budget of the United States Government. Office of Management and Budget, Washington, D.C., February 1984)]

The Need for Technical Talent

Without hesitation I would assign highest priority to stimulating and nurturing technical talent. During the past several years I have heard from hundreds of our nation's industrial and university leaders, and almost to a person they echo that priority. Now, especially as the economy has resumed strong growth, industries that depend on technical talent are feeling the pinch. In many of the fast-growing fields---the-ones-thatcreate new-jobs and products for export---there simply are not enough really good people to go around.

We face problems of both numbers and quality. We face problems that threaten to put a brake on the ability of our economy to continue to grow. For instance, in recent years there has been a pervasive and serious shortage of university faculty in engineering, computer sciences, and some of the physical sciences. These shortages have created bottlenecks in our ability to produce the kinds of technical talent most needed by growing U.S. industries.

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For that reason I think that one of the really exciting programs approved for fiscal year 1984 was the National Science Foundation's Presidential Young Investigator Awards. This program helps universities attract and retain outstanding young Ph.D.'s who might otherwise pursue nonteaching careers. It does so by generously funding research of faculty near the beginning of their academic careers.

The first 200 awards were made in February 1984, and NSF is preparing to award 200 more in 1985. Each recipient is eligible for 5 years of support at up to \$100.000 per year in a combination of federal and industrial funds. It is expected that 200 new investigators will be named each year, resulting after 5 years in a projected continuing total of 1000 active awards. Moreover, this program is flexible and able to respond to obvious shortages. Thus, more than three-quarters of the first awards went to young faculty in engineering and the physical sciences.

Part of the intent of this program is to attract faculty in fields where shortages limit our ability to meet the growing demands by students for training. It is what might be termed a first-order solution to an obvious problem. But there is much more that we can and must do. It is ironic that although the United States has the world's greatest research institutions and the most advanced industrial capacity, we simply have not developed effective linkages between them. We are now intensifying our efforts to do just that.

Both the academic and industrial communities have voiced growing concern about the kind of training we are providing for our engineering undergraduates the vast majority of whom expect to enter industry. We are in the midst of a revolution in the way engineers work and the way modern industry operates. That revolution is putting potent new computer tools in the hands of the product designer and blurring distinctions between disciplines.

Few universities, however, are able to prepare their students to operate in that new environment. This is not really their fault, but reflects a combination of a lack of modern equipment and overburdened faculty who are struggling just to keep up with teaching demands. We see several hopeful signs that promise to help them overcome those limitations. In particular, industry is helping universities plan for the kinds of working environments that new graduates will enter. At the same time, industry-with virtually no strings attached—is helping many schools directly by funding new programs and providing modern equipment for student use. Certainly, events in the past year suggest the dawning of a new age of enlightenment for engineering education.

The federal government clearly has a key role in this transformation. The nation is going to rely heavily on new generations of engineers for its industrial and economic health. Because of the competitive environment in which U.S. industry must operate, we have to help our universities provide the best training possible.

For the past 6 months the Office of Science and Technology Policy (OSTP), industry groups, the National Academy of Engineering, and NSF have been looking very hard at this problem. We have been looking particularly at the broad areas of design and manufacturing because those are critical processes to master in converting knowledge-which the U.S. research establishment produces in prodigious quantities-into products. What is emerging from this collaboration is a proposal for a new program at NSF in 1985 to create university centers for cross-disciplinary research in engineering.

The intent of such an ambitious program is to develop a body of knowledge to guide engineers in integrating different disciplines to work on problems of both national and industrial importance. At the same time it will help the universities, working closely and continuously

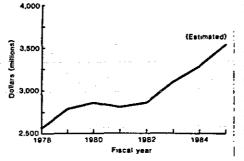


Fig. 3. Basic research obligations to universities and colleges in constant 1983 dollars. [Source: Office of Science and Technology Policy (from Special Analysis K: Research and Development, the Budget of the United States Government, Office of Management and Budget, Washington, D.C., 1984)]

with industrial affiliates, take a giant step in how they educate engineers. I believe that in the next few years we are going to see substantial and overdue changes in the way we approach academic engineering and that these centers are only the first of many innovations.

I emphasize that virtually every step being considered for improving the engineering schools is being taken in cooperation with industry. The new federal programs all encourage more productive interaction between industry and the universities—and both should benefit.

One important point is that these engineering centers will continue to require strong disciplinary research programs conducted in parallel in the universities. The hope would be that faculty and students would move freely back and forth between the centers and specific areas of research. Thus, at the same time that the centers are being started, for example. NSF has also requested a 22 percent increase in funds for engineering research. The purpose of that growth is not necessarily to permit more research projects, but to permit the best ones to be more productive by funding larger groups of investigators and by underwriting the purchase of equipment and instrumentation.

Instrumentation and Supercomputers

Because the instrumentation problem underlies virtually all basic research at universities, we have adopted a policy of building support in large part for new instrumentation and equipment directly into project grants. Across all R & D agencies, the federal government expects to provide more than \$400 million in 1985 for research instrumentation available for university scientists and engineers. This amount, while substantial, falls far short of the estimated needs. But those needs are the result of an extended period of underinvestment in university research instrumentation. and the problem cannot be solved all at once. Keeping up with new technology must be a continuing process, and we intend to provide these substantial sums of money on a continuing basis.

Our preference for including much of that support as part of actual researchgrants rather than as separate instrumentation programs is to emphasize that instrumentation is as much a part of modern research as any other expense: to permit instrumentation to be tied closely to highest priority research programs: and to give researchers as much discretion as possible in deciding how best to allocate research funds.

I would include one other specialized kind of equipment in any discussion of development of talent in universities. and that is supercomputers. It is simply imperative for our academic research community—faculty and especially students—to have opportunities to work with state of the art computing tools.

There are three main reasons for emphasizing the importance of these computing tools. One is the direct benefit to frontier research: supercomputers offer the best known way to attack many large-scale science and engineering problems. a way to model complex physical interactions. Second is the opportunity for young scientists and engineers to

Table 1. Federal R & D obligations

Table 1. Federal K & D obligations.							
Category	Fiscal year budgets (billions of dollars)					Change (%)	
	1981	1982	1983	1984	1985	1984– 1985	1981– 1985
Total federal R & D	\$35.0	\$37.6	\$39.5	\$46.7	\$53.1	14	52
Total defense R & D Basic research	\$16.5	\$20.9	\$23.2	\$28.1	\$34.2	22	107
Total	\$ 5.1	\$ 5.4	\$ 6.4	\$ 7.2	\$ 7.9	10	55
Agencies supporting life sciences	\$ 2.4	\$ 2.4	\$ 3.0	\$ 3.3	\$ 3.5	5	46
Agencies supporting physical sciences and engineering	\$ 2.7	\$ 3.0	\$ 3.4	\$ 3.9	\$ 4.4	14	63

learn what supercomputers can do and to become familiar with them. After all, these people are the ones who will be developing the supercomputer's potential for solving new kinds of problems in the future. And third is the vital contributions that the research community will make to designing and developing the software to make the supercomputers even more useful in the research process.

Both NSF and DOE plan to provide university researchers with more access to supercomputers both by allocating more time to them on supercomputers at national laboratories. such as through DOE's Magnetic Fusion Energy computing network, and by installing new supercomputing facilities dedicated to academic users. NSF also plans to install a class VII supercomputer at the National Center for Atmospheric Research for use by the atmospheric and ocean sciences community.

In parallel efforts, DOE, NSF, and DOD will increase research funds for various areas of computer science and electronics that will be applicable to future generations of supercomputers. We are confident that these varied activities, in conjunction with continued purchase of the most advanced supercomputers for direct government use, will, in turn, provide the market incentives to permit U.S. commercial manufacturers to maintain their technological leadership in this field.

The Pursuit of Excellence

The importance of project support to the vitality of universities and to their ability to train students is evident. But project support is also a primary means of addressing the parallel goal of science policy—the pursuit of excellence. The tried and true method of investigatorinitiated, peer-reviewed research grants has produced phenomenal results over the years. The fact that scientists at U.S. institutions won four out of four Nobel Prizes last year reflects on the effectiveness of this kind of system for supporting basic research.

Although there are many. I will offer only one specific example of a 1985 initiative intended to help American scientists continue to pursue excellence. A field of science in which this country has been a world leader and also a field that demands extremely careful—not to mention wise—decisions about future programs is high-energy. or particle physics. The questions the scientists ask are in many ways the most fundamental in nature, and the answers are surely among the hardest to find. Over the years there have been important direct applications of knowledge first derived from this kind of front-line physics research to other areas of science and technology.

But fields like this are important as much for the way they attract and stimulate human intellect as for their specific results. Particle physics, or astrophysics, or molecular biology. or mathematics are stimuli for our broad national strength in science and technology. Of those fields particle physics is the most expensive to pursue today. It is that expense that forces us to make, as I noted, wise decisions about what course we will pursue. It was that expense that led to a fundamental rethinking by the high-energy physics community, last year, of where this country should be going in particle physics.

The result of that introspection was the decision to terminate a major accelerator project that was no longer timely. Instead, the community is now focusing its attention on an entirely new accelerator that would let us take a bold step into new energy regimes. Such a step would permit us to look at truly forefront questions in the structure of matter.

Such a project has strong merit if it can be designed, if it can be built for a reasonable cost, and if it can be built in a reasonable time frame. Those are big "ifs," and I do not believe that anyone can yet tell us whether we can meet those requirements. But we are proposing that in fiscal 1985 we begin the process of trying to find out. To that end, DOE will begin R & D on advanced superconducting particle accelerator concepts.

This would permit us, at some point later in this decade, to decide whether or not to proceed with the next-generation machine, a superconducting supercollider. Questions of how, where, how much, and, perhaps, with whom must be deferred until we have a better handle on the technology. I emphasize that we propose no commitment to proceeding beyond this R & D: construction, should it appear feasible, will have to be decided upon later.

Partnerships with Industry

The third goal of science policy, stimulating partnerships among scientists and engineers in universities. federal laboratories, and industry, reflects the pressing need to improve the transfer and application of new knowledge to national needs, particularly in industry. There has been some real progress in the past few years in improving these interactions, not so much because of anything government has done as much as because of the broad national awareness of the obvious industrial and military challenges from abroad.

Better partnerships are clearly needed in the field of agriculture. There is little question but that we have made only slow progress in bringing the benefits of the modern biotechnology revolution to American agriculture. The result is that we have failed to take the prudent steps necessary to protect the enormous world leadership that we have enjoyed for so long in agriculture.

We have already seen-painfullyhow aggressive competitors who adopt new technologies and run with them can make severe inroads into what American industry assumed was a guaranteed market. Automobiles and consumer electronics come most readily to mind. We would hate to have to add agriculture to that list 20 years from now. Fortunately, we have tremendous resources in this country that should enable us to maintain and extend our world lead, but we have to start now to incorporate the fruits of molecular biology and its offshoots into a new field of agricultural biotechnology. To accelerate that process, the Department of Agriculture will greatly expand its competitive grants program in fiscal 1985. This will include a substantial new agricultural biotechnology research effort within that program.

Next year will also be a milestone for another kind of partnership with industry. It stems from the President's decision that the United States should begin work on defining and designing a space station. I would characterize this decision as recognition that we are going to occupy and use space on a larger scale than ever before. We will be simultaneously enlarging our ability to explore space and enlarging the nation's long- term options for creating a new base for industrial activity. It is clear that this activity demands broad involvement of the private sector to identify the highest priority industrial opportunities and to bring industry's expertise to planning systems to be tested and used in space.

At the same time we are committed to maintaining the momentum that we have built up in our very successful programs of research in the space sciences. New programs to start in 1985 include the Upper Atmosphere Research Satellite. the Mars Geoscience-Climatology Orbiter, and the Naval Remote Ocean Sensing Satellite. These join projects already under way, such as the Space Telescope. the Gamma Ray Observatory, the Galileo Jupiter probe, the Venus Radar Mapper, and a variety of Spacelab science programs. The United States has embarked on an incredibly promising and balanced space science program, one that will not be compromised by the manned space efforts but that will, in fact, complement them. We are all aware of the lesson of the impact of the Shuttle program on space sciences in the 1970's—and we are not about to see that happen again.

During the past year we also took important_steps_toward_making_betteruse of the nation's federal laboratories in meeting national needs. In light of the amount of R & D done there-more than one sixth of the total public and private sector R & D-it should be obvious that they should be expected to contribute to our attempts to rejuvenate American industry and universities. In July 1983 David Packard, on behalf of the White House Science Council, presented the results of a yearlong review of the federal laboratories to the President. Following that, the President instructed OSTP and the Office of Management and Budget to lead an interagency effort to work on ways to implement the recommendations. He also asked for a progress report by 1 July 1984.

The Packard panel had concluded that the nation could derive far more benefit from the federal laboratories. and it recommended changes in five major areas to help improve their effectiveness. Briefly, the panel called for clearer missions. for changes in personnel systems to attract and retain top technical talent. for more stable funding and more-autonomy for the laboratories in managing their research, and for broader interactions between the laboratories and other public and private sector R & D organizations.

The Administration's plan last year to pioneer a new kind of industry-university-federal laboratory interaction through establishment of a broadly based materials research center at Lawrence Berkeley Laboratory was an early indication of the kinds of actions the panel anticipated. During the past year the plans for the Center for Advanced Materials have benefited from thoughtful review and recommendations from the materials science community. recommendations that are being implemented. The original objectives for the center are unchanged-a place to bring together a range of materials and other scientists from all sectors to work on problems of fundamental importance to future technology.

Leapfrog Technologies

One other example, still in the very early stages, suggests yet another kind of potential for making better use of the federal laboratories. The President's Commission on Industrial Competitiveness, formed about 6 months ago, is a group of mostly private sector leaders who are looking at ways to strengthen U.S. industry. One of the concerns that surfaced early in their discussions was the obvious plight of what are called the basic industries—or the smokestack industries.

One commission member, the chairman of a major steel company, made it clear that the future of his industry in America, which has been losing its competitive advantage to foreign producers, was going to rise or fall in the long term on its ability to achieve substantial increases in productivity through the application of what he calls "leapfrog technology"—a new technological generation in steel manufacturing.

Whether such leapfrog technologies can be developed is an open question. The steel companies, through their research arm, have been working among themselves and with university researchers on just what might be possible and practical. What struck several of the public sector representatives was that the people working the problem were either largely unaware of the kinds of technical expertise in the national laboratories, or they assumed that such expertise was not available to them. In either case, we have taken steps to correct that perception.

The steel industry's problems are important far beyond the industry itself. and not only because of the strategic and economic impacts of a healthy steel industry. In fact, steel is only one of several industries facing similar, almost generic problems. The OSTP has taken this opportunity to serve as a kind of marriage broker between the industry and the federal laboratories, and research directors at the major steel companies have shown great willingness to work together on common problems in R & D. We are determined that their willingness to seek new ways to rejuvenate industrial R & D will be matched by a willingness in the public sector to try to help steelmaking prepare for the 21st century.

It was quickly obvious that these R & D problems being posed by the industry were interesting and important enough to elicit enthusiastic responses from the science community, and it may turn out that the OSTP broker's role will be short-lived. Indeed, it would be disastrous for Washington to become a permanent element in what has to be direct collaboration among working scientists and engineers. The sooner we step out of the process the better.

There is one additional point to emphasize. The initiative for this effort comes from the steel industry—from the people who know the problems and are charged with finding solutions that meet economic tests. For any industry that might benefit from leapfrog technologies, the first step in each case is for the industry itself to define its needs and then to cast a wide net for some new perspectives to apply to recalcitrant problems.

Importance of Consistency

The various examples of new activities in science and technology are intended to convey the directions and emphases in a federal policy that underwent some important changes in 1981. The projects cited are hardly meant to encompass all the important new projects for fiscal year 1985 but rather to illustrate some of the concrete ways in which policy becomes reality.

Above all. I believe that it is critical to be aware of the need for consistency in any policy for science. By their nature, science and technology demand longterm planning and preparation, starting early in the educational process and extending into the maturing of young researchers and their integration into the research, academic, or industrial communities. Major facilities may take a decade to develop and may be used for decades more.

The planning cycles for the world of science and technology are far longer than the turnaround times in the political arena, and one of the most serious detriments to good science is what is called roller-coaster funding. Those of us who accept the responsibility for charting the course for government programs in science and technology must also accept the responsibility for clearly articulating-and sticking to-basic principles for guidance. I see this consistency as a major element of science policy, an element that I hope the Administration. Congress, the science community, and the public will be able to maintain in coming years.

THE WHITE HOUSE

Office of the Press Secretary

For Im	mediate Release	August 30, 1984
	REMARKS OF THE PRESIDE	NT
	TO NASA EMPLOYEES	5007
		NEOB
	Visitor's Center	OSTP
1999 AND 19	Goddard Space Flight Cen Greenbelt, Maryland	

11:31 A.M. EDT

THE PRESIDENT: Thank you very much. Thank you. And thank you, Jim Beggs.

I'm a little self-conscious right now about arriving in kind of an old-fashioned way, in a helicopter. And after what I've seen here, I'm even more self-conscious about the fact that I'm a captain of the horse cavalry. (Laughter.)

But I'm delighted to be with you today and to have this chance to say congratulations on this morning's lift-off of the Discovery mission. I'm honored to meet all of you who are making this great adventure happen. You've sparked the dreams and imagination of the nation -- from the youngest boys and girls in classrooms across our country to individuals like myself who are approaching the outer limits of their middle-age years. (Laughter.)

You go quietly about your work, far removed from the glare and the gloss and the glitter of public spotlights. But what you do is important. You're expanding our wealth of knowledge, and with that knowledge, you're fueling a mighty tide of progress, carrying the hope of an optimistic future for people here and everywhere.

Yours is the work of a true revolution; not a revolution poisoned by hatred and violence and the will to conquer, but one that's rising from the deepest yearnings of the human spirit to challenge the limits of knowledge and to put the power of discovery at the service of our most noble and generous impulses for decency, progress, and, yes, for peace.

Today, on behalf of a greatful nation, I salute you and your colleagues in private enterprise and the academic world. You're the heroes of high-tech; the pulse of America's technological power; the champions of a confident people whose faith and courage are pushing America up and out to a world of wonders for us, our children, and our children's children.

The space age is barely a quarter of a century old, but already we have taken giant steps for all mankind. And our progress is a tribute to American teamwork and excellence. We can be proud that we're first, we're the best, and we are so because we are free.

MORE

There's nothing that the United States of America cannot accomplish, if the doubting Thomases would just stand aside and get out of our way. In a single generation, we've freed ourselves from the bounds of earth; we've set our footprints on the surface of the moon; we've used our instruments to explore space, the sun and our sister planets; and our space shuttle provides the first reusable space transportation system for research, commercialization of space, and scientific exploration.

Meeting these great challenges has given us benefits far more valuable than our original investments. It has proven wrong those dreary souls that lacked the vision to support your efforts. With their pessimism, America could never have gotten off the ground. With your space shuttle, we have again and again.

And I'm convinced your success confirms a vision that we share: an America unafraid, reaching into space with courage and leadership, will be an America unsurpassed. We have it within our power to create a bounty of new jobs, technologies and medical breakthroughs surpassing anything we've ever dreamed before or imagined.

We already benefit daily from a modern revolution in worldwide communications. We can communicate with each other at a moment's notice, virtually anywhere on the globe. We can anticipate tommorrow's weather and prepare for it. Our space shuttle system provides access to space for science, technology, communications and national security.

Only a few weeks ago, we watched the Olympics on television, sharing excitement with people all over the world. I can remember, and believe me it doesn't seem long ago, when we lived in the horse-andbuggy days of television. We couldn't see a breaking event on the other side of the world until the film was shipped here. But, today, thanks to your research and development work, we have modern communications satellites beaming crystal-clear telecasts worldwide.

Another quiet revolution in technology has also been driven, in part, by the rigors of our space program. New materials from plentiful natural resources like carbon and silicon are taking the place of expensive metals in virtually all manufactured products. Our automobile engineers in Detroit are using lightweight, superstrong, plastic-like materials to reduce the weight of modern cars -- and consumers are getting the benefits in the form of more miles to the gallon.

Computers using microchips are constantly redefining our world as they become smaller, more powerful, and less expensive. Those chips are the heart of inexpensive electronic calculators now commonplace in the workplace, community and classroom. Sometimes these technological changes take place so gracefully over time that we hardly notice them. Today, our children have access to more computer power than most professional scientists and engineers had in their laboratories at the beginning of the space age.

MORE

Dr. Robert Jastrow, Chairman of the First NASA Lunar Exploration Committee, predicted nearly two years ago that the computer industry would double in size by 1986, becoming America's biggest business. Already, tens of thousands of practical applications of space and aeronautical technology are touching our lives. I've just seen an exhibit here with a vast array of new products from life-saving vests for firemen to sophisticated aerial-scanning techniques to locate and identify everything from schools of fish to mineral deposits to healthy timberland.

In medicine, we're seeing the vision of technology with a human face with one miraculous breakthrough after another. The procedure called CAT scanning uses a computer to compile a clear picture from X-rays taken at different angles, often permitting patients to avoid the risks and discomforts of surgery. CAT scanning has come a lifesaver in detecting diseases of the brain and other vital organs.

The pioneer field of computer-controlled walking has given hope to thousands of paralyzed Americans that, someday, they may walk again.

The widespread use of sound waves allows doctors to avoid potentially harmful use of X-rays. Using sound waves to monitor the progress of babies inside the womb permits earlier diagnosis of problems, a safer pregnancy and delivery for the mother, and better health for the baby.

H.T.S., for Human Tissue Simulator, sends electrical impulses through wire leads to targeted nerve centers, or particular areas of the brain, providing relief from pain and stopping unwanted involuntary motion. I'm happy to point out that H.T.S. was sponsored by the Goddard Space Center.

I've also been shown a hand-held X-ray machine and the Programmable Implantable Medication System called PIMS that administers medication automatically within the body.

It would be difficult to put a pricetag on the value of these human benefits. Even more dazzling opportunities lie ahead, if only we have the faith and courage to keep pushing on. Each technological breakthrough enables us to work from a new and higher plateau. It opens the door to great leaps in productivity which would have been considered unthinkable only a few decades ago.

Permit me to suggest that the fraternity of pessimists, who today insist strong growth will ignite high inflation, are looking at abstract statistics, theories and models, not the reality of a changing world. They do not see that as we acquire more and more knowledge from new technologies, we no longer move forward in inches or feet, we begin to leap forward.

Working the zero-gravity environment of space, we can manufacture in just one month's time lifesaving medicines that it would take 30 years to manufacture on earth. And we can manufacture crystals of exceptional purity that may enable us to produce super computers and make even greater breakthroughs in productivity. Our vision is not an impossible dream, it's a waking dream. As Americans, let us cultivate the art of seeing things invisible. Only by challenging the limits of growth will we have the strength and knowledge to make America a rocket of hope shooting to the stars.

High technology is born from capital, and more capital will require continued incentives for risktaking and investment, not tax increases, which would stifle growth. We support high tech, not high taxes. The federal government must constantly endeavor to strengthen the private economy, while supporting research and development, particularly in universities, to train tomorrow's industrial and academic scientists and engineers.

Our agenda for excellence in education at the elementary and secondary school level is also crucial, so students, like those I met at Jefferson Junior High School on Monday, can acquire the knowledge to enter universities and, one day, step into these vital positions of leadership and responsibility.

Between 1981 and 1985 federal investment in basic research will have increased by almost 30 percent in real terms. And we will carry forward that strong commitment into the future. We will also continue our support of tax credits for industrial R&D expenses; and we'll strive to lessen concerns that cooperative R&D between companies may violate antitrust statutes.

With the power of economic growth, and the courage and determination of a free people, we can keep our number one challenge in space -- to develop a permanently-manned space station, and do it within a decade. From that space station, we can carry out the kind of work in medicines and crystals I mentioned a moment ago; we can conduct new research, explore the distant planets, and, at the same time, unlock the vast potential for commerce in space by easing tax laws and regulations which discriminate against commercial ventures. And we'll be doing all these things for the sake of a more peaceful and prosperous world.

America has always been greatest when we dared to be great. We will be leaders in space because the American people would rather reach for the stars than reach for excuses why we shouldn't. And as American technology transforms the great black night of space into a bright new world of opportunities, we can use that knowledge to creat a new American Opportunity Society here at home. We can ensure every person has not only an equal chance, but a much greater chance to pursue the American dream.

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To do this, we must maintain and increase our older industries' ability to compete in the world, stimulate creation of sunrise industries, and meet the challenge of ensuring American leadership and prosperity into the 21st century. Call me an optimist, but I'm convinced that if we do accept this challenge, if we maximize incentives, invest fully in the new technologies, and strive for the great breakthroughs in productivity, then, yes, we can out-produce, out-compete, and out-sell the pants off anybody, anywhere in the world.

We can build an America that offers productive, secure job opportunities for all our fellow citizens, from assembly line workers to research scientists in new industries such as biotechnology, robotics, and information processing.

We can meet our goal of assuring adequate supplies of affordable energy so that never again will the American people be held hostage by a foreign cartel.

We can apply new agriculture technologies to preserve our soil and environment, and dramatically enhance productivity through improvements in crop yields and resistance to disease and harsh environments. We can enhance our world leadership in agricultural production and in nutritional assistance to millions who look to America for hope and for help.

If we're to keep our economy healthy and strong, we need to stay healthy and strong ourselves. Our success will depend on each person's willingness to adopt healthy habits, our collective ability to improve an already effective health care system, and our continued research and pioneer work in the kinds of medical technologies you're developing right here. Before this decade is out, our administration is committed to reducing significantly the death rate for all age groups and to ensuring older Americans can live healthier, longer, and more productive lives. We can and we must.

The dream of America is much more than who we are or what we do. It is, above all, what we will be. We must always be the new world; the world of discovery, the world that reveres the great truths of its past, but that looks forward with unending faith to the promise of the future. In my heart, I know we have that faith. The dream lives on. America will remain future's child, the golden hope for all mankind.

Thank you for welcoming me today and thank you for all you do and thank you for your courage to dream great dreams. God bless you all. (Applause.)

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MR. BEGGS: Mr. President, if we may offer, and present a small token of our appreciation for your coming here today. know, on the last shuttle mission, we went up and repaired a ite. And that satellite -- the Solar Maximum Mission Satelitte -veloped here at Goddard, and indeed, the repairs were designed veloped here at Goddard and they were installed with cooperation the Houston Mission Control and the Houston astronauts, of course.

It was a very successful mission, and we now have another valuable scientific satellite working again for several years. model is a glass-blown model of that, showing the astronaut on his but, and we hope that it will remind you many times, both of the to Goddard, as well as the strong support that you have given his program and which we very much appreciate. And the encouragement you continue to offer -- we thank you for that very much.

Since the model is fragile, we'll deliver it to the Office. THE PRESIDENT: Thank you very much. (Applause.) ak you -- thank you very much.

MR. BEGGS: What do you do up there without a horse? sughter.)

THE PRESIDENT: Thank you all very much. And now, as a ttle girl told me in a letter a few years ago -- I'll get back to e office and go to work. (Laughter.) (Applause.)

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Dr. Roland W. Schmitt Senior Vice President – Corporate Research and Development General Electric Company

AAAS Colloquium on R&D Policy Shoreham Hotel Washington, DC March 25, 1983

About five years ago you couldn't open a newsmagazine without reading a title like "Vanishing Innovation" or "Has America Lost Its Edge?" or "The Declining Power of American Innovation". Today you can't open those same magazines without seeing the face of Steve Jobs of Apple, or Dan Filstra of Visicorp, or Nolan Bushnell who founded Atari and has already moved on through two other ventures. And when people in foreign countries such as Adam Osborne of Britain or Jesse Awieda, who was born in the Middle East, or H.P. Kwang of Korea get the urge to get in on the action and start their own computer companies, where do they do it? Do they move to Japan? No. They come to America.

A lot is said these days about the changes and new initiatives needed in this country's R&D enterprise. We hear a lot about how the Japanese and Germans do it, about the need for large federally funded, industrial R&D programs, the need to unleash the national labs to perform R&D for industry, the need for new tax incentives for industrial R&D and so on. All these represent changes in the way we go about pursuing technology development and industrial innovation.

But, before we rush off into new and untried approaches, we really need to look at the fundamentals of the system that has worked so well for the U.S. in the past. We need to make sure that these foundations are maintained in a healthy state, and that any changes we make are built on them. In our preoccupation with foreign competition and our rush into new dimensions of R&D policy, we need to remind ourselves of our own sources of competitive advantage, and our own indigenous strengths.

We already possess the building blocks of a strong, national R&D strategy. I have already alluded to one of these building blocks – our capability to generate fast growing, high technology firms. The climate the U.S. presents today to entrepreneurs is certainly one of our greatest strengths. So we should ask how to strengthen it, how to build on it?

One answer proposed in the past is tax incentives for venture capitalists. But I question whether blanket incentives to increase the amount of venture capital are really needed. In total, there is a lot of venture capital seeking opportunities in the U.S. today. East Coast venture capitalists establish offices on the West Coast, West Coast ones establish them on the East Coast, U.S. firms even establish offices in London and Paris – all looking for opportunities to invest. In addition, R&D limited partnerships, which are available to start-up companies as well as established ones, provide another source of venture capital. The overall availability of venture capital is not the chief limitation today.

Rather, the limitation in many places is the absence of a strong climate for nurturing new ideas and entrepreneurship. This is a lesson we should have learned from the great successes of the past – Route 128 and Stanford's Silicon Valley. They demonstrate that the growth of high technology firms only occurs in the context of a supporting environment – an environment with a strong technical infrastructure and with a general ambience of excitement about converting good ideas into successful businesses.

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We're seeing a spreading awareness of this fact to many campuses, many states, many localities. In fact, there's hardly a state left in this country that is not putting in place programs to nurture such supporting environments. New York State, for example, has taken strong new steps through its Science and Technology Foundation to activate and stimulate the many educational and financial resources within its own borders.

Skeptics argue that the states are over-reacting, that they will begin to compete with each other for the relatively scarce people with ideas good enough to turn into new ventures. But I disagree. What is scarce is not the potential for good ideas, but the supporting environment – the climate that activates latent entrepreneurs. In my view, the many efforts by states and localities are exactly the right approach.

My co-panelist, George Bugliarello, has certainly recognized this in the steps he is taking at the Polytechnic Institute of New York – PINY – to foster high technology start-ups, especially in the area of telecommunications. I'm pleased that the state of New York has recently recognized PINY's efforts as a center of excellence in telecommunications.

Among other initiatives that might be cited is one at Rensselaer Polytechnic Institute – RPI. It's called the Incubator Program. It's based on the premise that one of the main obstacles to the growth of small, high technology firms is the lack of a supporting environment during the crucial period between conception of an idea and its development to the point where it can be taken to the venture capitalist. All too often, the would be entrepreneur is forced to work on his ideas during this period in his spare time in a garage or basement workshop. As a result, many good ideas never take off. The incubator program at RPI – and others like it – is intended to fill this gap. Potential entrepreneurs are offered the supporting environment in which to incubate their good ideas. They pay RPI a low rent, and in return, receive office space on campus and free access to the RPI technical environment – facilities, libraries, and so on. In addition, they receive inexpensive consulting services from faculty, support work from students, and free assistance on how to put together a business plan and approach venture capitalists.

The program costs very little. But it is aimed at that stage of the innovation process in which small expenditures might make a big difference. Here is an imaginative policy tool that nurtures a unique American strength – and it's already at work.

The incubator program also illustrates how with a little imagination we can find new ways to use a second major building block of R&D policy – and one of this nation's oldest and greatest strengths – our system of research universities. It is encouraging to see that all elements of the political spectrum recognize the importance of these research universities and are calling for the steps necessary to maintain their vitality – including large increases in Federal budgets for R&D, such as the 18% increase proposed for the 1984 NSF budget. But the needs of our research universities – better faculty salaries, new facilities and equipment, more funds for research and for graduate student and post doc support – won't be met by a one-shot approach. It won't be easy to lure faculty, graduate students, and post docs back into academia – especially in the engineering disciplines. It will require a sustained effort for many years.

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One additional approach is to give universities high priority in the competition for federal basic research funds. In particular, they should not be put in the position of competing with the national labs for funding – as quite a number of universities now perceive themselves to be. When federal basic research funds flow to universities, several objectives are achieved simultaneously. The R&D is performed; but in addition, graduate students are trained through their participation in the research, graduate departments are able to attract better faculty with the lure of large research projects, and the growing financial crunch on universities is eased somewhat, since a portion of the federal funds support overhead, faculty salaries, student stipends, and research instrumentation. If we are really serious about the health of our universities, we should maximize the flow of federal funds for basic research to them.

Another vehicle for technology development that builds on resources already in place in the university system is the growing number of university-industry research arrangements. There's been enormous ferment in this area over the past few years. It is now hard to find a major university that does not have some sort of new institutional arrangement with industry.

We have research parks, industry affiliate programs, industry supported research institutes, cooperative industrial associations that fund university research – a variety of arrangements that have grown in response to the competition from abroad and to the need to drive this country back into technological leadership. Again the institutional arrangements are building from the bottom up. It has not taken intervention by the federal government to create this trend. It's been going on for decades, although some of the ideas and arrangements are new. The U.S. already has a greater tradition of effective industry-university cooperation than any other nation in the world.

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It is true that of late this has sometimes been a troubled relationship in the area of biotechnology. The contrast between the untroubled university spin-offs in microelectronics and computer technology and the troubled ones in biotechnology has puzzled me. But a venture capitalist friend, who has invested in some of the biotechnology start-ups, pointed out that these firms were largely still in the research stage and making their early money on research contracts, not on the specific product ideas that have fueled so many of the successful microelectronics ventures. So there are new issues in this type of industry-university relationship that do have to be addressed.

Let's turn now to another of our strengths – our industrial R&D capability. It is in this area that some of the most ambitious proposals for major new changes are being made. One set of proposals calls for strengthening the incentives for industrial R&D. We have already made significant gains in this area through the R&D tax credit and the provisions for faster capital cost recovery. But as we consider these and other changes, we ought to keep their potential benefit in perspective.

There already exists in this country an incentive for technological innovation_that_is_far_more_effective_than_any_incentives_that_might_be_created_by_new_ government policies. It's called competition in open markets.

The most important incentive for investment by industry in R&D is market-driven competition – competition with the Japanese, competition with the Germans, competition amongst ourselves. It's the reason any firm invests in R&D. It's the reason R&D spending in industry is increasing and now exceeds federal R&D spending.

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And that R&D isn't going solely into the creation of new high-technology industries, as important as they are. It's also going into the use of advanced technology to revitalize our core and service industries – whether it's new integrated power semiconductors to make motors more efficient, or new robots to build appliances more productively, or a computer-based expert system to help a repairman do his job better. So as we consider tax incentives and changes in patent policy, let's just keep in mind that the single most effective incentive for industrial R&D is this market-driven competition.

What's more, when we consider the many proposals for federal intervention, for federally funded industrial R&D centers for example, we should remember the failures of the past. In particular, we have to avoid the energy R&D syndrome – where we poured billions of dollars in the 1970's into the development of energy technologies intended for a market that could not absorb them.

In successful industrial R&D labs, the greatest challenge is transferring technology from the laboratory into new or ongoing businesses – even though the lab and the business reside in the same firm. When you try to transfer technologies between institutions from different sectors of the economy – from the government to industry for example – technology transfer becomes much harder.

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So let me propose a very simple principle by which to guide our thinking about federally supported industrial R&D. The motivation for the work must come from the firms that would ultimately use the technology to be developed. Unless the Federal Government is itself the ultimate customer, it should support industrial R&D only when the firms that would use the results of that R&D express a clear need for it, and back up that expression of need with substantial sharing of the costs on a competitive basis.

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As an example of what I mean by a clear expression of need, consider the recently formed consortium of electronics firms – the Microelectronics and Computer Technology Corporation. Now, the consortium is not receiving federal funding, but it represents a clear case in which firms in an industry perceive an R&D need, and commit themselves to meeting that need. Admiral Bobby Inman, the consortium's director, estimates that the first year's budget will be at least 75 million dollars – and that's funds generated from the member firms themselves. It's this kind of commitment that is required for successful technology transfer – and it's this kind of commitment that is often missing when the federal government rushes to fill a supposed gap in industrial R&D. If the intended recipients of the technology do not express a clear interest, and if they aren't willing to kick in a sizable portion of the funds, chances are that the R&D will not be transferred to industry.

There is one area, though, where government and industry have a good record of successful technology transfer – where the government itself is the prime customer. The leading example here is national defense – the last of the building blocks of technology policy that I'll talk about. Large defense budgets are a fact of life and the part of these expenditures that supports R&D could be a great asset to the commercial and industrial sectors of our economy.

Some Americans look with envy on Japan's cooperative, government sponsored program on very-large-scale integrated circuits. But, in fact, we've got a program that should make the Japanese envy us – if we use it right. It's called the Very High Speed Integrated Circuit, or VHSIC Program. It's aimed at the next generation of microelectronics, and at making sure that the circuits created in that next generation can be widely used in military systems. Already contracts have been granted to a dozen companies and one university totalling \$165 million. And the

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participants are matching each dollar they get from the government. By the time the program is finished, it could well involve total expenditures - public plus private - on the order of a billion dollars.

It builds upon a successful, time tested tradition in this country, one that began with aircraft engines, computers and semiconductors. Defense dollars are used to develop generic technologies that have widespread, important civilian applications.

Consider supercomputers, for example. The recent NSF study "Large Scale Computing in Science and Engineering" graphically points out the growing possibility that the U.S. may lose the lead in supercomputers to the Japanese. It proposes a national goal of a computer able to perform from 100 to 1000 times as many calculations per second as today's fastest computer. And it indicates the wide range of fields – from quantum theory to computer-aided engineering – that would benefit in a major way from this capability.

Supercomputers are vital to such national security needs as cryptography and weapons systems design. They offer industry ways for modeling things that today can't be modeled. This could lead to new types of airfoils and aircraft with greatly reduced drag, turbines and engines with sharply increased efficiency, improved oil exploration and better utilization of known reserves, better understanding of crack initiation and propagation in alloys, new ways to design parts from plastics, new techniques in computer-aided engineering, important advances in theoretical physics and chemistry, better weather prediction, and perhaps even dramatically improved materials designed using basic theoretical principles.

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The supercomputer is a prime example of a technology in which defense should take the lead. It would clearly benefit the military. But at the same time it would be giving U.S. computer firms the opportunity to advance the state of the art in ways that most of them can't afford at this point, because the market for such computers is small, even though they provide a big benefit to users.

I realize that what I am advocating here appears to fly in the face of the growing concern over the loss of technology to the Eastern bloc. So let me address that issue. First, there is the question of so called "dual use" technology – technology with both civilian and military applications. The prevalence of this "dual use" technology is usually cited as the reason for clamping down on civilian technology.

But the notion of "dual use" technology is misleading: at a sufficiently fundamental level, all science and technology is dual use. Certainly, there is widespread <u>generic</u> technology that has both civilian and military uses. But these technologies can and must be extended and specialized for the military application. I believe that altogether adequate protection of military technology is available at the application specific level. This provides the opportunity to protect the specific military use while leaving the underlying generic technology free for civilian use.

For example: to counteract the Soviets' propensity to "back-engineer" circuits they illegally acquire, I believe technology might be developed to permit a military form of microelectronics that would be virtually immune to back-engineering. Certainly it's worth a serious look.

As another example, surely the technology of making military circuits immune from radiation damage can be classified and used exclusively for military

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applications without encumbering the underlying generic technology of microelectronics for advanced commercial purposes. And there must be many more examples of how "dual-use" generic technologies can be specialized for military applications while leaving the generic parts free. This strategy would be far more desirable than the alternative of fatally encumbering our underlying ability to generate new technology.

That ability depends far more than non-technologists understand on leaving technical groups and individuals as free as possible from bureaucratic controls of any sort – even those imposed for ostensible security reasons. The "protection" of technology implies the regulation of technology and regulation implies slowing down and encumbering the generation of technology.

Why do you think the U.S. is so good at developing the technology that the Soviets want to steal? Why are they so poor at it? I submit it has a lot to do with the oppressive bureaucratic ambience that constantly surrounds the Soviet technologist. Do we now want to encumber our system in the same way? And especially, do we want to bring the one part of our system that <u>is</u> still working well to a halt without correcting the part of it already working less effectively than the Soviets — namely, the militarily specific development and deployment. It's ironic that one would even think it necessary to regulate the part of the system where we are clearly beating them in order to correct the part where they are beating us.

On that note, let me sum up. We have today in America the basic building blocks we need to regain technological leadership. We've got a climate for venture capital that's never been better ... the world's greatest university system ... an industrial base that's moving aggressively into high technology areas, spurred by competition ... and a defense effort that, in this era of dual-use technology, can be an enormous asset.

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We need to become more aware of these strengths ... to nurture the ones that are emerging ... and to strengthen the ones that are full-grown and protect them against well-meaning but misguided assaults in the name of protecting domestic industry, or in the name of military security. None of the policies I've heard talked about under the name technology policy can have nearly as much effect on the future as the strengths we already have in place. While being receptive to new ideas, we must not forget the strengths we already have. We must build our future by identifying, understanding, and using those existing strengths.

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R AND D AND INNOVATION: SOME EMPIRICAL FINDINGS* National Bureau of Economic Research

Edwin Mansfield University of Pennsylvania

Introduction

Conference Oct. 1981

Until about twenty years ago, economists neglected the study of technological change, with adverse effects on both the quality and usefulness of economic analysis. During the past twenty years, a substantial corpus of knowledge has been developed in this area, and much of it is being used by policy makers in both the public and private sectors. But despite the advances that have been made, the gaps in our knowledge are very great. The economics of technological change, while healthy and growing, is still at the stage where many of the basic facts, concepts, and theories are missing.

In the past two years, I have been engaged in a number of interrelated studies of R and D, innovation, and technological change. These studies have been concerned with a variety of topics, ranging from the composition of R and D expenditures to international technology transfer, from price indexes for R and D inputs to the effects of government R and D on private R and D. At this point, many of these studies have reached the point where some of the major findings are in hand, even though much more remains to be done before our understanding of the relevant topics is reasonably satisfactory.

The purpose of this paper is to bring together and discuss some of the empirical findings that have emerged. To keep the paper to a reasonable length, I shall have to be very selective and brief. Only a few findings of each study can be presented. In a sense, this paper provides a partial and preliminary overview of some of the recent work I have been doing in this area. Since the various studies are interrelated in many ways, such an overview should be

useful.

2. Composition of R and D: Effects and Determinants

To begin with, let's consider the composition of R and D expenditures. In my opinion, economists have devoted too little attention to this topic. For both analytical and policy purposes, the total R and D figures are hard to interpret because they include such a heterogeneous mixture of activities. Basic research and applied research are mixed up with development. Long-term projects are mixed up with short-term projects. Projects aimed at small product and process improvements are mixed up with projects aimed at major new processes and products. Process R and D is mixed up with product R and D. To answer many important analytical and policy questions, it is essential to disaggregate R and D.

Unfortunately, very little work has been done on this score. To help fill this gap, I have tried to (1) estimate the effects of the composition of an industry's or firm's R and D expenditures on its rate of productivity increase (when its total R and D expenditures are held constant), (2) investigate the relationship between the composition of a firm's R and D expenditures and its innovative output, as measured by the number of major innovations introduced, and (3) determine what factors are associated with the composition of a firm's R and D expenditures, particular attention being directed at firm size and industrial concentration.¹

At least four findings seem to emerge from these studies. First, holding constant the amount spent on applied R and D and basic research, an industry's rate of productivity increase between 1948 and 1966 seems to have been

directly related to the extent to which its R and D was long-term. Although the interpretation of this result is by no means clear-cut, it certainly is suggestive. As pointed out elsewhere,² many firms tend to concentrate on short-term, technically safe R and D projects. Particularly in recent years, some observers, including both public policy makers and top officials of the firms themselves, have begun to question the wisdom of so great an emphasis of this sort.

Second, when a firm's total R and D expenditures were held constant, its innovative output seemed to be directly related to the percentage of its R and D expenditures devoted to basic research. The data on which this result is based pertain to the chemical and petroleum industries, areas where we have accumulated a considerable amount of data concerning the R and D and innovative activities of particular firms. It would be extremely useful if a similar sort of investigation could be made of other industries. In view of the roughness of both the data and the analysis, this finding should be viewed as preliminary and tentative. In particular, it is hard to tell whether basic research is really the relevant variable, or whether it is a surrogate for something else.

Third, based on data obtained from 108 firms that account for about onehalf of all industrial R and D expenditures in the United States, it appears that the composition of a firm's R and D expenditures is related to the firm's size. But the relationship is not as simple as one might think. Whereas the largest firms seem to carry out a disproportionately large share of the basic research (and perhaps the long-term R and D) in most industries, there is no consistent tendency for them to carry out a disproportionately large share of the relatively risky R and D or of the

R and D aimed at entirely new products and processes. Instead, they generally seem to carry out a disproportionately small share of the R and D aimed at entirely new products and processes. These results are not contradictory. Basic research is by no means the same thing as R and D aimed at entirely new products and processes. Also, since both basic research and applied R and D can be relatively risky, the riskiness of a firm's R and D need not be closely correlated with the percentage of its R and D devoted to basic research.

Fourth more concentrated industries devote a smaller, not larger, percentage of R and D expenditures to basic research. This relationship is statistically significant, but not very strong ($r^2 = .46$). Relatively concentrated industries also tend to devote a relatively small, not large, proportion of their R and D expenditures to long-term projects and to projects aimed at entirely new products and processes, but the correlation (in each case, r^2 is about .09) is far from statistically significant. While there is a positive correlation ($r^2 = .15$) between an industry's concentration level and the proportion of its R and D expenditures going for relatively risky projects, this correlation too is far from significant.

3. Price Indexes for R and D Inputs

Not only is relatively little known about the composition of R and D expenditures. Equally important, the available data concerning real R and D expenditure are bedeviled by the lack of a suitable price index for R and D inputs. In view of the inherent difficulties and the strong assumptions underlying the few alternative measures that have been proposed, the official government R and D statistics use the GNP deflator to deflate R and D expenditures. Many observers inside and outside the government are uncomfortable with this procedure, but very little is known about the size or direction of the errors it introduces.

To help fill this basic gap, we constructed price indexes for R and D inputs and for inputs used in other stages of the innovative process. Very detailed data were obtained from 32 firms in the following eight industries: chemicals; petroleum; electrical equipment; primary metals; fabricated metal products; rubber; stone, clay, and glass; and textiles. These industries account for about half of the company-financed R and D in the United States. Although our sample contains both large and small firms, it includes a substantial proportion of the R and D carried out in these industries. Indeed, the firms in our sample account for about one-ninth of all company-financed R and D in the United States.³

At least four findings stem from this study. First, for these industries as a whole, the Laspeyres price index for R and D inputs indicates that the price of such inputs was about 98 percent higher in 1979 than in 1969. However, the rate of inflation in R and D seems to have been higher in some industries than in others. In particular, the rate of inflation seems to have been highest in fabricated metal products, chemicals, and petroleum, and

lowest in electrical equipment.

Second, turning to the innovation process as a whole, Laspeyres price indexes indicate that the price of inputs into all stages of the innovative process was about 101 percent higher in 1979 than in 1969. Thus, the rate of inflation for inputs into all stages of the innovation process seems to have been somewhat higher than for R and D alone. As in the case of R and D, the rate of inflation for inputs into all stages of the innovation process seemed to be highest in fabricated metal products, chemicals, and petroleum, and lowest in electrical equipment.

Third, if we assume that the production function for R and D in each industry is Cobb-Douglas (with constant returns to scale), an exact price

index for each industry is

 $I = \prod_{i=1}^{n} \left(\frac{P_{1i}}{P_{0i}} \right) \times 100$

where the price of the ith input in 1979 is P₁₁, its price in 1969 is P₀₁, d₁ is the proportion of R and D cost devoted to the ith input, and n is the number of inputs.⁴ Even though there is little or no information concerning the nature of the production function for R and D, it is interesting to compare the resulting indexes with the Laspeyres indexes because, since Laspeyres indexes ignore <u>substitution effects</u>, they may exaggerate price increases. Table 1 shows the results for each industry. As you can see, those based on the Cobb-Douglas assumption are/quite similar to those based on the Laspeyres indexes. Fourth, in practically all of the industries included here, the rate of increase of the price index for R and D inputs exceeded the rate of increase of the GNP deflator. Because of the inadequacies of the GNP deflator for this

purpose, the official U.S. statistics concerning deflated R and D expenditures seem to overestimate the increase during 1969-79 in industrial R and D performance. For these industries as a whole, deflated R and D expenditures increased by about 5.2 percent based on the GNP deflator, but only by less than one percent based on our price indexes for R and D inputs. Taken at face value, this seems to indicate that the bulk of the apparent increase in real R and D in these industries was due to the inadequacies of the GNP deflator.

On the average, the Colle - Douglad indeger indicate that the price of Rand Dinputer man it 200 percent higher m 1979 than in 1969.

(1)

Industry	يري التساريبيين الاستانيين المستعدين المستعدين المستع	yres Index Innovation Process	Cobb-Dougla R and D
Chemicals	222	223	217
Petroleum	222	228	218
Electrical equipment	183	186	190
rimary metals	205	210	205
Fabricated metal products	248	275	222
Rubber	209	200	206
Stone, clay, and glass	205	195 👻 🗍	183
Textiles	200	220	220

Table 1--Price Indexes for R and D Inputs and for Inputs in the Innovative Process, Eight Industries, 1979 (1969 = 100).²

The three columns are not entirely comparable because some firms could be included in some columns, but not others, because of lack of data.

^bFach industry's price index is weighted by its 1969 R and D expenditure.

Source: see Section 3.

4. Effects of Federal Support on Privately Financed R and D

Just as the lack of R and D price indexes has long been recognized, so it has long been pointed out that more needs to be known concerning the effects of government R and D on private R and D. This is an area that has been the subject of considerable controversy. Some economists argue that increases in government R and D funding are likely to reduce the R and D expenditures of the private sector because (among other reasons) firms may receive government support for some projects they would otherwise finance themselves. Other economists say that government R and D is complementary to private R and D, and that increases in the former stimulate increases in the latter. It is universally recognized that this question is of great importance both for policy and analysis, but little is known concerning it.

To shed light on the effects of federal support on privately financed -R-and D in the important area of energy, we chose a <u>sample of 25 major</u> firms <u>in the chemical</u>, <u>oil</u>, <u>electrical</u> equipment, and primary metals industries. Together they carry out over 40 percent of all R and D in these industries. To estimate the extent to which these firms obtained government funding for energy R and D projects that they would have carried out in any event with their own funds, we obtained detailed data on this score from each of the firms. Moreover, even more detailed data were obtained concerning a sample of 41 individual federally funded energy R and D projects. These projects account for over 1 percent of all federally supported energy R and D performed by industry.⁵

The following are some of the conclusions stemming from this study. First, it appears that these firms would have financed only a relatively small proportion of the energy R and D that they performed with government support. Based on our sample of firms, they would have financed only about 3 percent if the government did not do so. Based on our sample of individual projects, they would have financed about 20 percent if the government did not do so. It would be very useful if similar estimates of this sort could be obtained for various kinds of R and D outside the field of energy.

Second, if a 10 percent increase were to have occurred in federal funding for their energy R and D in 1979, the response (for all 25 firms taken as a whole) would have been that, for each dollar increase in federal support, they would have increased their own support of energy R and D by about 6 cents per year for the first two years after the increase in federal funds. In the third year after the increase, there would be no effect at all. This finding is based on careful estimates by senior R and D officials of each firm. It is worth noting that there are substantial differences among firms in their response. Note too that the results are quite consistent with those obtained by Levin (1980) and Terleckyj and Levy (1980) in their econometric studies of the aggregate relationship between federally funded R and D expenditures and privately funded R and D expenditures.

Third, if a 10 percent cut were to have occurred in federal funding for their energy R and D in 1979, the response (for all 25 firms taken as a whole) would have been that, for each dollar cut in federal support, they would have reduced their own support of energy R and D by about 25 cents in each of the two years following the tax cut. In the third year after the federal cut, there would have been about a 19 cent cut in their own spending. Taken at face value, it appears that a 10 percent cut in federally funded energy R and D would have a bigger effect on privately funded energy R and D than would a

10 percent increase. But until more and better data are obtained on this

score, we feel that this difference should be viewed with considerable caution. Fourth, in modeling the effects of federally funded R and D on the economy, our results indicate that it may be more realistic to view such R and D as a factor that facilitates and expands the profitability of privately funded R and D, rather than focus solely (as most econometric studies have done) on the direct effects of federally funded R and D on the productivity of the firms and industries performing the R and D. Based on our sample of federally funded projects, it appears that such projects typically make only about half as large a direct contribution to the firm's performance and productivity as would be achieved if the firm spent an equivalent amount of money on whatever R and D it chose. But in about one-third of the cases, the federally financed R and D projects suggested some further R and D into which the firm invested its own funds. (As shown in Table 2, the likelihood of such), a spinoff is enhanced if the firm helped to formulate the ideas on which the project was based,⁶ and if the project was not completely separated physically from the projects financed by the firm.) If federally funded R and D is viewed in this way, econometricians may have more success in measuring its effects on productivity in the private sector.

5. Forecasts of Engineering Employment

Engineering manpower is one of the most important inputs required in the complex process leading to innovation and technological change. Policy makers in government, universities, and business must make decisions that depend, explicitly or implicitly, on forecasts of the number of engineers employed in various sectors of the economy at various points in time. For example, in evaluating the adequacy of existing engineering manpower, the

Table 2.--Percentage of Federally Financed Energy R and D Projects Resulting in Company Financed R and D Done Subsequently by the Performer, by Source of Idea for Project and Extent of Separation from Company Financed Projects, 40 Projects^a

in san san san san san san san san san sa	Characterístic o	f Project	99999999999999999999999999999999999999	ليويتي ويو و المراجع	Samaayaa Hijofiya Jaabaana da katara katara jara a 1954 kaana da maaga aa ay aha	Percentage
	Source of Idea f	or Project:	· · · · ·			
	Firm Government Both Firm a	nd Governmen	nt			44 15 44
•	Separation:					
•	Complete Not Complet	é		•		17 38

Source: see Section 4.

One project could not be included because it was not yet clear whether it would result in company financed R and D. The figures in this table may understate the true percentages because they pertain only to company financed R and D resulting directly and almost immediately from these projects. National Science Foundation and the Bureau of Labor Statistics must try to forecast how many engineers will be employed in the private sector. Although such forecasts sometimes are based on a collection of forecasts made by firms of their own engineering employment, very little is known about the accuracy of firms' forecasts of this kind.

To help fill this gap, a very detailed econometric study was carried out. Data were obtained from a well-known engineering association which has collected such forecasts from firms for many years. For 54 firms in the aerospace, electronics, chemical, and petroleum industries, comparisons were made of each firm's forecasted engineering employment with its actual engineering employment during 1957 to 1976. Since data were obtained concerning a number of forecasts of each firm, the accuracy of 218 such forecasts could be evaluated.⁷

At least three conclusions seem to stem from this study. First, there appear to have been substantial differences among industries in the accuracy of the forecasts. As shown in Table 3, the forecasting errors for individual firms in the aerospace industry were much greater than in the electronics, chemical, or petroleum industries. (In chemicals and petroleum, firms' twoyear forecasts were off, on the average, only by about 5 percent.) The relatively large forecasting errors in the aerospace industry seem to be due to its heavy dependence on government defense and space programs which were volatile and hard to predict.

Second, although the forecasting errors for individual firms were substantial, they tend to be smaller when we consider the total engineering employment for all firms in the sample. On the average, the 6-month forecasts were in error by about 2 percent, the 2-year forecasts were in error by about 1 percent, and the 5-year forecasts were in error by about 3 percent. The fact that there was so little bias in the forecasts is encouraging since, for

Actual Employment	Aerospace	Electronics	Petroleum	Chemical	
					-
	Number of 6-mo	nth forecasts			
0.81-0.90	0	1	0	0	•
0.91-1.00	8	10	12	6	
1.01-1.10	7	9	13	9	-
1.11-1.20	0	2	0	1	
1.21-1.30	2	0	0	0	
1.31-1.40	2	0 -	0	0	
	Number of 2-ye	ar forecasts			
					•
0.61-0.70	0	1	0	0	
0.71-0.80	2	3	0	0	
0.81-0.90	4	3	4	1	
0.91-1.00	2	1	8	1	
1.01-1.10	3	6	6	5	
1.11-1.20	. 0	0	0	0	
1.21-1.30	• • • 0	3	0	0	
1.31-1.40	3	0	. 0 .	0	
		<u></u>		· <u>····································</u>	 .
Source: see Section 5.			•		•
a				· · · · · ·	
^a Five-year and ten-y not in this table.	ear forecasts	were also inclu	uded in the s	tudy, but	•
NOT IN CHIS LADIE:		nen an eine general eine eine generale der eine seine seine seine seine eine der seine seine der Staffendart			201102
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				and the second	

Table 3.--Frequency Distribution of Forecasts, by Ratio of Forecasted to Actual Engineering Employment, Aerospace, Electronics, Petroleum, and Chemical Industries, Six-Month and Two-Year Forecasts^a many purposes, the central aim is to forecast total engineering employment in an entire sector of the economy, not the engineering employment of a particular firm.

Third, the firms' forecasts may be improved if a very simple econometric model is used. Based on data for over a dozen chemical and petroleum firms, the proportion of the way that a firm's engineering employment moves toward the desired level is inversely related to the desired percentage increase in engineering employment⁸ and directly related to the profitability of the firm. (A similar model was used in Mansfield (1968).) Using information concerning this relationship in the past as well as the firm's desired level of engineering employment in the future, one can forecast the firm's future engineering employment. The evidence, while fragmentary and incomplete, suggests that experimentation with such an approach may be worthwhile.

5. International Technology Transfer

To understand a wide variety of topics, ranging from economic growth to industrial organization, economists must be concerned with international technology transfer. In my opinion, economists interested in the relationship between R and D and productivity increase have paid too little attention to international technology transfer. In practically all econometric models designed to relate R and D to productivity increase, international technology flows are not included (explicitly at least). Yet U.S.-based firms carry out about 10 percent of their R and D overseas, and this R and D has an effect on the rate of productivity increase in the United States. In addition (and probably more important), R and D carried out by one organization in one country often has a significant effect on technological advance and productivity increase in another organization in another country. For example, productivity

increase in the American chemical industry was certainly influenced by the work of Ziegler in Germany and of Natta in Italy.

To shed new light on the process of international technology transfer, we have carried out several types of studies. One study was concerned with the channels of international technology transfer and the effects of international technology transfer on U.S. R and D expenditures. Another study was concerned with the size and characteristics of overseas R and D carried out by U.S.-based firms. Still another study dealt with the transfer of technology by U.S.-based firms to their overseas subsidiaries.⁹ Based on these studies, it seems to me that economists should reconsider some of the models that have been used most frequently to represent the process of international technology transfer.

The traditional way of viewing the process of international technology transfer has been built around the concept of the product life cycle.¹⁰ According to the product life cycle, there is a fairly definite sequence in the relationship between technology and trade, whereby the U.S. tends to pioneer in the development of new products, enjoying for a time a virtual monopoly. After an innovation occurs, the innovator services foreign markets through exports, according to this model. As the technology matures and foreign markets develop, companies begin building plants overseas, and U.S. exports may be displaced by production of foreign subsidiaries. The concept of the product life cycle has had a great influence in recent decades because it has been able to explain the train of events in meny industries.

At least four of our findings seem relevant in this regard. First, our data suggest that the situation may be changing, and that the product life cycle may be less valid than in the past. By the mid-1970s, in the bulk of the cases we studied, the principal channel through which new technologies were exploited abroad during the first five years after their commercialization

was foreign subsidiaries, not exports. (See Table 4.) About 75 percent of the technologies transferred by U.S. firms to their subsidiaries in developed countries during 1969-78 were less than five years old. Based on our data, the "export stage" of the product cycle has often been truncated and sometimes eliminated. Particularly for new products, firms frequently begin overseas production within one year of first U.S. introduction. In some industries, such as pharmaceuticals, new products commonly are introduced by U.S.-based firms more quickly in foreign markets than in the United States (due in part to regulatory considerations).

Second, there seems to be a difference in this regard between products and processes. For processes, the "export stage" continues to be important (Table 4). Firms are more hesitant to send overseas their process technology than their product technology because they feel that the diffusion of process technology, once it goes abroad, is harder to control. In their view, it is much more difficult to determine whether foreign firms are illegally imitating a process than a product.

Third, to a large extent, this change in the process of international technology transfer and trade reflects the fact that many U.S.-based (and foreign-based) firms have come to take a worldwide view of their operations. At this point, many of them have in place extensive overseas manufacturing facilities. As indicated above, many also have substantial R and D activities located abroad. Given the existing worldwide network of facilities and people, firms are trying to optimize the operation of their overall operations. This may mean that some of the technology developed in the United States may find its <u>initial</u> application in a Canadian subsidiary, or that an innovation developed in its Canadian subsidiary may find its <u>initial</u> application in the firm's British subsidiary, and so on.

. Table 4Percentage Distribution of R and D Projects, by Anticipated	Channel
of International Technology Transfer, First Five Years After	c .
Commercialization, 23 Firms, 1974	

•		Foreign		echnology T	Joint	,
		Subsidiary	Exports	Licensing		Total ^a
All R and D Projects ^b	and devices the based of the second secon	74	15	- 9	2	100
Projects aimed at: ^C	•			· · ·	~	
Entirely new product		72	4	24	· 0 ·	100
Product improvement		69	9	23	0	100
Entirely new process		17	83	0	0	100
Process improvement	•	1.5	52		3	100.

Source: see Section 6.

^aBecause of rounding errors, percentages may not sum to 100.

^bThis is the mean of the percentage for 16 industrial firms and for 7 major chemical firms. The results are much the same in the two subsamples. Only projects where foreign returns were expected to be of some importance (more than 10 percent of the total for the first subsample and 25 percent of the total for the second subsample) were included.

^COnly the chemical subsample could be included.

Fourth, the product life cycle is less valid than it used to be because technology is becoming increasingly internationalized. For example, in the pharmaceutical industry, it no longer is true that a new drug is discovered, tested, and commercialized, all within a single country. Instead, the discovery phase often involves collaboration among laboratories and researchers located in several different countries, even when they are within the same firm. And clinical testing generally becomes a multi-country project. Even in the later phases of drug development, such as dosage formulation, work often is done in more than one country. In contrast, the product life cycle seems to assume that innovations are carried out in a single country, generally the United States, and that the technology resides exclusively within that country for a considerable period after the innovation's initial commercial introduction.¹¹

7. "Reverse" Technology Transfer

"Reverse" technology transfer is the transfer of technology from overseas subsidiaries to their U.S. parents. (Because the principal flow of technology is generally in the opposite direction, this is often called the "reverse" flow.) In some quarters, there has been a tendency to dismiss technology transfer of this sort as unimportant. Yet practically nothing is known about the extent and characteristics of "reverse" technology transfer, even though such information obviously would be of relevance to public policy makers concerned with the technological and other activities of multinational firms.

To determine the extent to which overseas R and D by U.S.-based firms has resulted in technologies that have been applied in the United States, we obtained data pertaining to 29 overseas R and D laboratories of U.S. firms in the chemical, petroleum, machinery, electrical equipment, instruments, glass, and rubber industries. This sample of overseas laboratories, chosen essentially

at random from those of major firms in these industries in the Northeast, accounts for about 10 percent of all overseas R and D spending by U.S.-based firms. The industrial and geographical distribution of the sample is reasonably similar to the industrial and geographical distribution of all overseas laboratories, according to the National Science Foundation and other data 12 sources.

The following three findings help to put "reverse" technology transfer into better perspective. First, over 40 percent of these laboratories' 1979 R and D expenditures resulted in technologies that were transferred to the United States: Thus, such transfer is common and by no means insignificant. However, there are vast differences among overseas laboratories in the percentage of R and D expenditures resulting in technologies transferred to the U.S. Most of this variation can be explained by three factors: (1) whether the laboratory's primary function is to produce technology for worldwide application, rather than to service or adapt technology transferred from the U.S. or to produce technology for foreign application, (2) the laboratory's total R and D expenditures, and (3) the percentage of its total R and D expenditures devoted to research, rather than development.

Second, there is a very short lag (on the average) between the data when a transferred technology first is applied abroad and the date when it is first applied in the United States. Indeed, in the electrical equipment firms in our sample, the average lag is negative. Because of the size and richness of the American market, firms tend to introduce new products (and processes) based on technologies developed in their overseas laboratories about as quickly in the United States as in their overseas markets. These results indicate the extent to which firms take a global view of the introduction of innovations.

As pointed out in the previous section, this is a departure from the situation years ago.

Third, based on our data, there is a tendency for more recently developed technology to be transferred more quickly to the United States than technology developed years ago. Also, technologies yielding relatively large profit in the United States were transferred more quickly than those that were less profitable here.

Fourth, although much of the R and D carried out overseas is directed at the adaptation and improvement of existing technology, overseas R and D laboratories have generated technology that was the basis for new products and other innovations that contributed billions of dollars in profits to U.S. manufacturing firms in 1980, if the laboratories in our sample are representative in this respect.

8. Overseas R and D and U.S. Productivity Growth

As pointed out in section 6, "reverse" technology transfer-is not included (at least explicitly) in existing models of K and D and productivity growth. Indeed, because the official R and D statistics have excluded U.S. firms' overseas R and D expenditures until recently, previous studies of the relationship between a firm's or industry's R and D expenditure and its rate of productivity increase have ignored overseas R and D. Obviously, it would be interesting and useful to include U.S. firms' overseas R and D in such models and to see how much, effect it has on domestic productivity growth.

To do this, it is convenient to use essentially the same model as that *Maxifield* (1968, 1980), employed by Grilliches (1980), **Constant and Terleckyj** (1974), except that research and development is disaggregated into two parts: domestic R and D and overseas R and D. In a particular firm, the production function is assumed

$$Q = Ae^{\lambda t} R_{d}^{\beta_{1}} R_{o}^{\beta_{2}} L^{\gamma} K^{1-\gamma}, \qquad (2)$$

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where Q is the firm's value added, R_d is the firm's stock of domestic R and D capital, R_o is its stock of overseas R and D capital, L is its labor input, and K is its stock of physical capital. Thus, the annual rate of change of total factor productivity is

$$f = \lambda + \theta_1 \frac{dR_d/dt}{Q} + \theta_2 \frac{dR_o/dt}{Q} , \qquad (3)$$

where $\theta_1 = \partial Q / \partial R_d$ and $\theta_2 = \partial Q / \partial R_o$. And based on the usual assumptions,¹³

$$P = \lambda + a_1 \frac{X_d}{Q} + a_2 \frac{X_o}{Q} , \qquad (4)$$

where X_d is the firm's domestic R and D expenditure and X_o is its overseas R and D expenditure in the relevant year.

My econometric results pertain to 15 chemical and petroleum firms, for which I have estimated ρ for 1960-76. (See Mansfield (1980).) For each of these firms, I obtained data concerning X_d/Q and X_o/Q , the results being shown in Table 5.¹⁴ Estimates of a_1 and a_2 could be obtained by least squares, the results being

These results have at least two implications. First, they indicate that overseas R and D, as well as domestic R and D, contributes to productivity growth in the United States. The estimate of a_2 is positive and statistically significant. More surprisingly, the estimate of a_2 is much larger than that of a_1 , indicating that a dollar's worth of overseas R and D has more effect on domestic productivity increase than a dollar's worth of domestic R and D. But this difference is not statistically significant. For most firms, I doubt that

Firm	$\frac{x_d}{Q}$		•	x ₀ Q
2010/1012/2010/101-101-1010/101/101/101/101/101/101		ána a sa an		
2	.0890		1 A. 14 A.	.0043
3	.0715			0
4	.0610			.0024
5	.0770			0 .
6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	.0820		tan. Kabupatèn di kabupatén kabupatén kabupatén kabupatén kabupatén kabupatén kabupatén kabupatén kabupatén kabupaté	.0091
7	.0101			0
8	.0061		• • · · ·	.0003
9	.0072		ж ¹ .	.0001
10	.0068			0 .
11	.0114			0
. 12	.0118			.0001
13	.0073	* + -		0
14	.0087			.0020
15	.0147	· · · · · ·	an a dha An	0

Table 5.--Values of X_d/Q , and X_o/Q , 15 Chemical and Petroleum Firms^a

Source: see Section 8.

^aThe data concerning X_d/Q and X_d/Q pertain to a year in the mid-1960s (1963 to 1965). It was not possible to get data for precisely the same year, but the results should be sufficiently comparable for present purposes. a₂ is as large as a₁, based on our other studies. But be this as it may, equation (5) certainly buttresses our findings in the previous section concerning the nontrivial nature of reverse technology transfer.

Second, these results allow for the first time a glimpse of the size of the bias that may have resulted from the omission of overseas R and D expenditure in past studies of this sort. If X_0/Q had been omitted from equation (5), the result would have been

> $= .022 + 0.28X_d/Q.$ (6.61) (3.95)

Thus, a would have been higher than if both overseas and domestic R and D were included. If this case is at all representative, the rate of return from domestic .R and D may have been overestimated in previous studies, since a has often been interpreted as such a rate of return.

9. Imitation Costs, Patents, and Market Structure

In the previous three sections, we have been concerned with the transfer of technology from one nation to another, where the transferor and transferee often are parts of the same firm. Now let's turn to the transfer of technology within the same nation, where the transferor and transferee are different firms, and where the transfer is involuntary from the point of view of the transferor. In particular, suppose that one firm imitates (legally) another firm's innovation. How much does it cost? How long does it take? How often does it occur? Economists have long recognized the importance of these questions. For example, they frequently have pointed out that, if firms can imitate an innovation at a cost that is substantially below the cost to the innovator of developing the innovation, there may be little or no incentive for the innovator to carry out

23

(6)

the innovation. Yet there have been no attempts to measure imitation costs, to test various hypotheses concerning the factors influencing them, or to estimate their effects.

To help fill this important gap, we obtained data from firms in the chemical, drug, electronics, and machinery industries concerning the cost and time of imitating (legally) 48 product innovations.¹⁶ Imitation cost is defined to include all costs of developing and introducing the imitative product, including applied research, product specification, pilot plant or prototype construction, investment in plant and equipment, and manufacturing and marketing startup. (If there was a patent on the innovation, the cost of inventing around it is included.) Imitation time is defined as the length of time elapsing from the beginning of the imitator's applied research (if there was any) on the imitative product to the date of its commercial introduction. For present purposes, four findings of this study seem of particular interest. First, innovators routinely seem to introduce new products despite the fact that other firms can imitate these products at about two-thirds (often less) of the cost and time expended by the innovator. In our sample, imitation cost averages about 65 percent of innovation cost, and imitation time averages about 70 percent of innovation time. There is considerable variation among products in the ratio of imitation cost to innovation cost. Much of this variation can be explained by differences in the proportion of innovation costs going for research, by whether or not an innovation was a drug subject to FDA regulations, and by whether or not an innovation consists of a new use for an existing material where some firm other than the innovator has patents on this material.

Second, the magnitude of imitation costs in a particular industry seems to have a considerable impact on the industry's market structure. How rapidly

a particular innovation is imitated depends on the ratio of imitation cost to innovation cost. Also, an industry's concentration level tends to be low if its members' products and processes can be imitated easily and cheaply. The latter relationship is surprisingly close. Apparently, differences among industries in the technology transfer process (including transfers that are both voluntary and involuntary from the point of view of the innovator) may be able to explain much more of the interindustry variation in concentration levels than is generally assumed.

Third, in most cases, patents seem to have only a modest effect on imitation costs, as shown in Table 6. However, in the ethical drug industry, patents seem to have a bigger impact than in other industries. According to the firms, about one-half of the patented innovations in our sample would not have been introduced without patent protection. But the bulk of these innovations occurred in the drug industry. Excluding the drug industry, the lack of patent protection would have affected less than one-fourth of the patented innovations in the sample.

Fourth, patented innovations seem to be imitated surprisingly often and quickly. In our sample, about 60 percent were imitated within four years of their initial introduction. Reality seems to depart sharply from the commonlyheld belief that a patent holder is free from imitation for the life of the patent. In my view, it is very important that this fact be taken into account by the excellent economic theorists working in this area, since there sometimes has been a tendency for models of the innovation process to assume that the innovator receives all of the benefits from an innovation, and that imitation has can be ignored.

Table	6Estimated Percent	tage Increa	ase in	Imitation (Cost I	ue to Pateni	ts,
•	33 New Products,	Chemical,	Drug,	Electronics	s and	Machinery	
	Industries. ^a						

Percent Increase in Imitation Cost	Number of Products
Under 10 10 - 19 20 - 49 50 - 99 100 - 199 200 and over Total	13 10 4 0 3 3 3

Source: see Section 9.

^aNot all innovations in our sample are included here, because not all were patented or patentable.

10. Innovation and Market Structure

In recent years, economic theorists have also begun to focus on the effects of innovation on market structure. Of course, it has long been recognized that technological change is one of the major forces influencing an industry's market structure. Karl Marx stressed this fact over a century ago. But the renewed interest is welcome, since traditional models of the relationship between innovation and market structure have been deficient in many respects.

Unfortunately, empirical findings on this score have also been relatively scanty. Very little is known concerning the effects of major recent process innovations in various industries on minimum efficient scale of plant. Almost nothing is known about the effects of major recent product innovations in various industries on the extent of concentration. To help fill this gap, I obtained information from 24 firms in the chemical, petroleum, steel, and drug industries concerning the effects of over 65 process and product innovations that were introduced in the past half century.

Although this study is still in a relatively early phase, several findings seem to be emerging. First, in the chemical and petroleum industries, the bulk of the process innovations resulted in increases in minimum efficient scale of plant. In steel, only about half of the process innovations resulted in such increases, but most of the rest had little or no effect on minimum efficient scale. Thus, in all three industries,¹⁸ scale-increasing innovations far outnumbered scale-decreasing innovations.¹⁹ However, although relatively few major innovations in these industries have reduced minimum efficient scale, a substantial proportion have had no appreciable effect on it.

Second, the evidence in these industries does not support John Blair's

well-known hypothesis (1972) that, since World War II, fewer innovations tend to increase minimum efficient scale than in the past. To test this hypothesis, I compared the proportion of process innovations introduced after 1950 that resulted in such an increase with the proportion introduced before or during 1950 that did so. Contrary to Blair's hypothesis, the proportion was higher, not lower, in the later period.

Third, in all four industries combined, less than half of the product innovations in the sample seemed to increase the four-firm concentration ratio. The percentage was particularly low in drugs. The fact that only a minority of these major new products increased concentration in these industries is noteworthy, given the common tendency among economists to view technological change as a concentration-increasing force. If these industries are at all representative (and if this preliminary result holds up in my subsequent work), there should probably be more emphasis on innovation's role in reducing and limiting existing concentration.²⁰

11. Conclusions

The findings presented here have a number of implications for public policy. With respect to government R and D policy, they suggest the following: (1) In their attempts to promote productivity increase, policy makers should recognize the importance of long-term R and D and basic research. (2) Policy makers should also recognize that much of the apparent increase in real industrial R and D during 1969-79 may have been a statistical mirage, due to the lack of better price indexes for R and D inputs. (3) Changes in federally financed R and D expenditures (at least in energy) are unlikely to be offset to any appreciable extent by changes in privately financed R and D; on the contrary, such changes

seem to induce changes in the same direction in privately financed R and D. (4) To the extent that policy makers want to increase the spillover from federally financed to privately supported R and D, the results suggest that firms should be encouraged to work with government agencies in the design of federally financed R and D projects, and that the separation of such projects from firms' company financed R and D projects should be reduced.

With respect to patent policy, the findings seem to suggest that, outside pharmaceuticals and agricultural chemicals, patents frequently are not regarded as essential by innovators. Excluding drug innovations, more than threefourths of the patented innovations in our sample would have been introduced without patent protection. In a minority of cases, patent protection had a very major effect on imitation costs and delayed entry significancly, but in most cases it had relatively little effect. Obviously, these findings have important implications concerning the role of the patent system in stimulating technological change and innovation.

With regard to antitrust policy, our findings shed new-light on the relationship between an industry's concentration level and the nature of its technological activities. Highly concentrated industries seem to devote a relatively low percentage of their R and D to basic research, and there is an inverse (but not significant) relationship between an industry's concentration ratio and the percentage of its R and D that is long-term or aimed at entirely new products and processes. Also, our results (covering the chemical, drug, petroleum, and steel industries) provide new information about the frequency with which major new products result in increases in concentration. In our sample, many new products (particularly in drugs) seem to have been introduced by firms that "invaded" the relevant market or that were not among the leaders in that market. This

is not to argue that innovations do not frequently increase concentration. But it does suggest that the role of innovation in undermining existing concentration may sometimes be underestimated.

With respect to national policies concerning international technology transfer and the multinational firm, our findings underscore the extent to which technology is transferred across national boundaries, the difficulties and costs involved in trying to stem the technological outflow from U.S. firms to their foreign subsidiaries, and the benefits to the United States from the inflow of technology from these subsidiaries. "Reverse" technology flows are becoming increasingly important. Based on our econometric results, overseas R and D has a considerable effect (per dollar spent) on productivity in the U.S. These facts should be taken into account in the evaluation of the role of multinational firms in contributing to technological change and economic growth in the U.S.

Our findings should also be of use to industrial managers. Faced with the difficult task of choosing an R and D portfolio, managers badly need evidence concerning the relationships between the composition of a firm's R and D expenditure, on the one hand, and its innovative output and rate of productivity increase, on the other. Also, they need more sophisticated and reliable indexes of the rate of inflation in R and D in order to budget their resources properly, and they can benefit from improved techniques for forecasting engineering employment.

Besides being of interest to policy makers, we believe that the findings have some implications for economic analysis. In my opinion, models relating R and D to productivity change should go further in disaggregating R and D, in taking account of international technology flows (and, in some cases, interindustry technology flows), and in using better R and D price indexes.

For many purposes, it may also be useful to view government R and D as a factor that expands the profitability of private R and D. With regard to the role of technology in international trade, the product life cycle model should be altered or supplanted to recognize the changes that have occurred in this area. Further, students of industrial organization should devote more attention to the measurement and analysis of imitation costs (and times); this is a central concept that has been ignored entirely in econometric work.

In conclusion, the limitations of the studies described here should be noted. Although many of the samples (of firms, R and D projects, innovations, and so forth) are reasonably large, they nonetheless cover only certain industries or sectors of the economy. In many instances, the theoretical models we use are highly simplified. No pretense is made that the findings presented here are the last words on the subject. Nonetheless, we believe that these findings shed new light on a wide variety of major topics about which relatively little (often, practically nothing) has been known.

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Footnotes

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¹Some results of these studies have been published in Mansfield (1980). Additional results will appear in Mansfield (forthcoming). Link (1981) also has been investigating factors associated with the composition of R and D.

²For recent evidence on this score, see my forthcoming article in the Harvard Business Review.

³This work is being carried on with Anthony Romeo and Lorne Switzer. For a preliminary account of some of our findings, see Mansfield, Romeo, and Switzer (1981). For some previous work, see Goldberg (1978). Also, S.A. Jaffe has worked on a price index for academic R and D expenditures for the National Science Foundation.

⁴For a proof of this, see <u>ibid</u>.

⁵This work is being conducted with Lorne Switzer.

⁶Of course, we recognize the difficulty in many cases in identifying where the ideas underlying a particular project originated. But in the cases in Table 2, this generally seemed to be a matter of agreement among all parties.

This work was done with Peter Brach. Some of the results will appear in Brach and Mansfield (forthcoming).

⁸This model assumes that desired employment exceeds actual employment, which was the typical case in these firms in the relevant time periods. Obviously, this model should be used only in cases where this assumption is true.

See Mansfield, Romeo and Wagner (1979), Mansfield, Teece, and Romeo (1979), and Mansfield and Romeo (1980).

¹⁰See Vernon (1966, 1970).

¹¹See Mansfield et al. (forthcoming).

¹²This work is being done with Anthony Romeo.

¹³ These assumptions are described in detail in Mansfield (1980).

¹⁴One firm included in Mansfield (1980) could not be included here because it is part of a foreign-based multinational firm. The data concerning X_d/Q and X /Q were obtained from the firms.

¹⁵Tests were carried out to determine whether an industry dummy variable should be included in equation (5). The results provide no statistically significant evidence that this should be done.

¹⁶This work was done with Mark Schwartz and Samuel Wagner. Some of the results will appear in Mansfield, Schwartz, and Wagner (forthcoming).

¹⁷The lists of innovations came from Mansfield (1963), Mansfield et al. (1977), and Landau (1980).

¹⁸The drug industry was excluded here because of its emphasis on product innovation.

19 This seems to be in accord with the observed changes in minimum efficient scale in these industries. See Scherer (1980).

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²⁰In their paper on this subject, Nelson and Winter (1978) emphasize the concentration-increasing effects of innovation. However, they are careful to point out that their computer simulations represent a "partial view," not a "general model."

NEXT

Intellectual Property Rights in Brazil

I. Overview

Protection of intellectual property rights is an important problem in Brazil, and one that has not yet been effectively addressed in bilateral or multilateral fora. U.S. companies operating in Brazil have long been aware of these problems and have developed a variety of strategies for dealing with them. Cases of infringement of these rights that have come to the attention of the USG have been dealt with on an <u>ad hoc</u> basis. Brazil has a growing reputation for violating intellectual property rights.

This paper is based primarily on information provided by the U.S. private sector. In general, <u>protection of property rights</u> <u>in Brazil suffers from weak enforcement, inadequate criminal</u> <u>penalties and some official resistance to support foreign</u> <u>rightsholders</u>. Protection under patents and trademarks has suffered from application of <u>compulsory licensing provisions</u>. A consensus of U.S. companies believes that Brazilian intellectual property laws as written are acceptable except in the case of pharmaceuticals, but problems arise because of the way they are interpreted and enforced.

The issue of intellectual property rights is presently crystallizing with regard to protection of <u>computer software</u>. Following passage of a highly restrictive informatics law, a new computer software bill was presented to the Brazilian Congress at the close of the 1984 session. The bill, which would restrict the term of protection and establish compulsory <u>licensing</u> provisions, will provide the basis for discussion in the 1985 Congress. This is the same pattern followed in passage of the Informatics Law, which eventually gained such widespread popular support that it became unstoppable. If the software bill becomes law, activities of U.S. firms in the Brazilian market will be severely affected.

The National Institute of Industrial Property (INPI) is the key institution for the protection of intellectual property rights in Brazil. By all accounts, it is poorly managed, understaffed and hostile to foreign interests. Some discussion with INPI has occurred as a result of negotiations in the Monsanto patent infringement case. A general dialogue, however, needs to be established, before there can be hope for real progress. Brazilian perceptions of the functions and purposes of a system of intellectual property rights protection diverge sharply from those of the U.S. A bilateral mechanism for discussion could be established along the lines of the Brazil/France Cooperation Agreement.

The current overall situation amounts to a severe disincentive to U.S. direct investment in Brazil, particularly in high tech product categories, and second only in impact to Brazil's market reserve policies. II. Background

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- A. Patents
 - 1. Issues

a. Adequacy of Legal Protection

1. Scope of Protection

No patent protection is available for pharmaceutical, animal health or food products. On chemical inventions, "compound" claims are prohibited, but composition, production process and method of use claims are allowed. However, enforcement problems (see below) greatly reduce the protection provided in this way. Also excluded from protection are micro-organisms and anything resulting from transformation of the atomic nucleus.

Lack of patent protection for pharmaceuticals has had serious economic consequences for U.S. companies. In some cases, sales of unauthorized copies of U.S. innovations by Brazilian "pirate" companies equal or exceed sales by the innovators themselves. The patent term of fifteen years from date of filing is considered too short by many U.S. firms.

2. Compulsory Licensing

If a patent is not worked in Brazil within threeyears of issuance, or if its use is interrupted for more than a year, or if there is not sufficient supply of the product to meet demand, the National Institute of Industrial Property (INPI) may release it for compulsory licensing to interested parties. This period is too short for complex technologies and those requiring governmental approvals prior to exploitation. "Working" is defined as regular industrial utilization (not import) by patentee or licensee. The patent holder must submit evidence of working and royalty payment to INPI each year. When compulsory licensing takes place, the patentee is required to provide the compulsory licensee with all the technology required to practice the licensed patent. This amounts to forced disclosure and encourages piracy.

In a case involving a major chemical manufacturer, a patent covering a process, a composition and a use was licensed to a Brazilian company because one of the patent's claims was not being used. <u>According to this interpretation all types of claim</u> <u>in a patent must be worked for "working" to be</u> <u>effective</u>. This is illogical and a disincentive to the introduction of new technology.

b. Adequacy of Enforcement and Legal Sanctions

According to U.S. companies, Brazil has a long history of lax enforcement of patent rights. Before 1971, many international firms did not even bother to register patents, since court action to prevent violations was considered ineffective. Most large companies depend principally on their sophiscated technology and the heavy capital reguirements of their operations to protect them.

Both civil and criminal actions are available against a patent infringer. However, <u>proceedings</u> <u>are very slow</u> and there is a reluctance to imprison an infringer or grant adequate damages. <u>Neither</u> <u>preliminary nor permanent injunctions are</u> <u>available</u>. Hence, the only recourse is to obtain an early decision from the court as to the fine to be imposed for continued infringement and hope that the amount of the fine acts as a deterrent. During the period of infringement, the infringer learns how to manufacture the patented product efficiently; when the patent expires (15 years from the date of original application) the infringer has already established a market position.

<u>Since 1982 all chemical composition claims have</u> <u>been rejected by INPI</u> despite an Appeals Court decision that composition claims were allowable if the components together produced a distinct effect. Enforcement of "<u>method of use" claims</u> in chemical patents is <u>impractical</u> because there is no legal concept of "contributory infringement" or "inducement to infringe". The only available legal remedy is to sue each individual consumer. For "process" claims, Brazilian examiners are requiring the inclusion of <u>trivial process parameters</u> which make the claims much easier to "work around".

c. Fairness and Complexity of Registration Procedures

As in the United States applications are handled case-by-case, with those offering more sophisticated or badly needed technology receiving 'favored treatment. Average time for approval is about two years. INPI is understaffed and has been known to "borrow" technicians from other government agencies.

Patented agricultural chemicals must be registered with the Ministry of Agriculture and obtain a "toxicological classification" prior to commercilization. This requires submission of a complete toxicology package. However, once obtained, the <u>toxicological classification is</u> <u>considered generic</u> and may become available to subsequent registrants.

d. Restrictions on Licensing

Strict registration requirements for licensing agreements together with severe limitations on royalty remittances cause this to be an area of great conflict between foreign companies and the Brazilian government. Royalty payments from a subsidiary to a parent are prohibited and royalties between non-affiliated parties are permitted only within strict limits (1-5% of gross sales.) The concept itself of a license is significantly diminished. The licensor can place no restrictions on a licensee's use, disclosure or disposal of a technology beyond a period which is usually five years or less. There can be no restriction on a licensee's exports or the source of imported raw materials or components. These limitations are a significant disincentive to patenting new technology in Brazil. Since royalties cannot be paid to an affiliate, any payment by a subsidiary for use of a patent must be included within profit remittances (limited to 12% of registered capital, net of withholding, or else liable to tax penalties). Under U.S. tax law, the parent will still be liable for the royalties which should have been paid by the Brazilian subsidiary. Patents or proprietary technology are not considered part of a foreign company's investment in Brazil and therefore, are not figured into the capital base against which profits may be remitted.

GOB agencies play a direct role in determining the commercial conditions in licensing contracts. U.S. firms consider this inappropriate. Remittance of fees and royalties is controlled by INPI and the Central Bank. Payments cannot be made until registration of patents is approved and licensing agreements have been registered at the Central INPI passes judgment on the rate of Bank. remittance and the value of technology, and a requirement now exists that Brazilian companies consult INPI before concluding negotiations. Companies that have allowed lower royalty payments by Brazilian companies than by other licensees world-wide have had difficulty when the Brazilian firm began to export. INPI does not allow royalties on the Brazilian firm to be raised to the level of other firms manufacturing the product.

d. Participation in International Agreements

Brazil is a signatory to the Paris Convention and has signed bilateral arrangements with several Latin American countries.

e. Local Private Sector Programs - None

- 2. Suggested Solutions (these apply likewise to trademark problems)
- a. Fact Finding
- Obtain information on patent filing trends in Brazil for illustrative use with GOB on success of their current program; compare with Mexico.
 - Use private sector information to investigate advantages/disadvantages of a bilateral industrial property cooperation agreement.
- Examine usefulness of industry Section 303 submissions as case studies to illustrate intellectual property problems for future talks with Brazil.
- b. Government-to-Government Consultations
 - Use bilateral trade and investment discussions to convey to the GOB the seriousness of intellectual property problems as perceived in the U.S., and enlist their cooperation in resolving the problems.
 - Work with the interagency GSP committee to ensure that intellectual property protection problems in Brazil are carefully considered in determining the level of Brazil's GSP benefits. Apprise the Brazilians of the importance of these problems in the review process.
- Investigate possibility of proposing to Brazilians that decision-making be raised to political level in determining when "national interest" overrides intellectual property protection rights of foreigners.
- Propose regular consultations with INPI.
- c. Offer Solutions
- Offer technical assistance for reevaluation of Brazilian intellectual property rights protection framework in light of Brazil's growing reputation for violating intellectual property rights. Continue to invite Brazilian officials to participate in PTO training programs.
- Explore with PTO and the private sector the feasibility of sending an educational mission on intellectual property protection to Brazil in FY 1986.
- Educate U.S. firms planning investments about intellectual property rights problems they can expect to face in Brazil

3. Assessment for Progress

According to our private sector, disrespect for intellectual property rights is firmly entrenched in Brazil. The GOB appears willing to consult, but the legislation is such that certain problems, including payments and patent protection for pharmaceuticals, will not be easily remedied.

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Progress can be expected to come only on an issue-by-issue basis until a dialogue on the overall subject can be established.

B. Trademarks

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Issues

a. Adequacy of Legal Protection

The Brazilian trademark system does not recognize prior use, so that rights over a trademark are obtained through first filing. There have been a number of cases of legal registration of a foreign trademark in Brazil by a party with no relationship to the foreign owner of the trademark. The trademark may be registered for the purpose of taking advantage of a world-wide reputation or advertising, or in order to sell the registration to the rightful owner. There are many instances of well-known trademarks being registered for unrelated goods. Brazilian Trademark Law only recognizes well-known marks that are "supernotorious". To obtain such recognition the foreign trademark must be well-known throughout the Brazilian territory at all economic levels.

Special treatment is given to pharmaceutical and veterinary trademarks, allowing coexistence of similar trademarks as long as they are applied to products having the same therapeutic effects.

b. Adequacy of Enforcement and Legal Sanctions

<u>Trademark infringements</u> by small entrepreneurs are <u>quite common</u>, especially in the consumer product area. Informal actions are the usual way of resolving most problems. Infringement is so common that large numbers of prospective infringers may simultaneously apply for registration of the same trademarks.

If a foreign company pursues and wins a trademark infringement case, the local producer may still capitalize on the issue through advertising implying it has been victimized by a giant multinational corporation. c. Fairness and Complexity of Registration Requirements

Delays in trademark registration have recently been reduced.

d. Use Requirements

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Brazilian trademark law provides that a registration is subject to cancellation if the trademark has not been used for <u>two years</u> from the issuance of the registration or when use of the mark has been discontinued for more than two years. This is too short. <u>It frequently takes longer than two years to</u> <u>commercialize a product</u>. However, in order to prevent other parties from registering the mark, it is necessary to file a trademark application well before commercialization. Under these provisions, if the mark is registered more than two years before the product is commercialized and the trademark is not used, the trademark owner may lose his trademark.

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<u>Due to severe import restrictions, foreign trademarkowners often have difficulty meeting use requirements.</u> The "force majeure" justification is under dispute due to contradictory INPI decisions.

e. Participation in International Agreements

Paris Convention Arrangement of Madrid Inter-American Convention of Buenos Aires

2. Suggested Solutions

- Convince INPI to make administrative changes to give greater consideration to "force majeure" as an obstacle to meeting use requirements, and to recognize well-known marks more easily.
 - Establish bilateral agreement like the France-Brazil agreement to promote cooperation in the area of protecting industrial property.

3. Assessment for Progress

Regular consultations with INPI could bring about improvement.

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C. Copyright

1. Issues

a. Adequacy of Legal Protection

While Brazilian copyright law is generally in accordance with international norms, there are a number of chronic difficulties, such as <u>video piracy</u>, <u>inadequacy of criminal penalties</u>, lack of enforcement <u>and some resistance from officials to support foreign</u> <u>rightsholders</u>. U.S. industry has complained that the Brazilian requirement of an <u>affidavit in addition to</u> <u>the U.S. certificate of copyright</u> is an unreasonable evidence requirement for bringing suit for copyright infringement. Brazilian copyright law is flexible enough to accord protection to automated data bases under works of compilation authorship.

1. Software

Discussion is currently taking place in Brazil on the kind of protection that should exist for computer software. The lack of copyright protection for computer software has deterred many U.S. suppliers from offering their latest software to the Brazilian market. At a recent WIPO meeting, the Brazilian representative indicated that copyright protection for software was unacceptable and that Brazil preferred a sui generis form of protection including: an abbreviated term of protection (most likely fifteen years), compulsory licensing, and registration of source code. Japan's recent adoption of copyright protection has left Brazil isolated as the only major country opposing copyright protection. The Brazilian courts have not determined that copyright protection applies to computer software. Several cases of copyright infringement of computer software are currently before the Brazilian courts. The courts recently found that copying had not taken place in a case in which Sinclair Research alleged that its software had been illegally copied. Lotus is currently proceeding against a company said to have applied for registration of a program based on Lotus 1-2-3. U.S. companies believe that the courts will not make a clear determination until the political decisions have been made.

2. Translation rights

Authors maintain the exclusive right of translation. Translators may not oppose the making of new translations unless the author has delegated the exclusive right of translation. Translations

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of original works that receive prior authorization from the author and do not jeopardize the original works are considered new intellectual works. Authorized translations are subject to copyright protection. There are no issues in this area at present.

3. Compilation

In the case of a collection of works (made up of articles or extracts from the works of different authors), each author retains the rights with respect to his own product. As long as they do not jeopardize the rights of the authors of the component works, compilations are protected as independent intellectual works.

b. Adequacy of Enforcement and Legal Sanctions

Brazil's copyright statute provides for civil and administrative sanctions that do not prejudice applicable criminal sanctions.

<u>Widespread piracy in Brazil has caused great concern</u> <u>among motion picture producers and distributors</u>. The problems include frequent unlicensed showings, videocassette piracy and imports of unauthorized videocassettes. It has been estimated that at the end of 1984, one million pirated cassettes were available.

U.S. companies report that it has been difficult to obtain guilty findings where copyright infringement is alleged.

c. Fairness and Complexity of Registration Procedures

Under Brazil's copyright statute, registration is not a precondition to copyright protection. Registration is free of charge.

d. Participation in International Agreements

Brazil is a signatory to both the Universal Copyright and Berne Conventions.

e. Local Private Sector Programs

N/A

2. Suggested Solutions

We should encourage Brazil to apply copyright protection to computer software through continued high level demarches. We should also encourage the GOB to raise their concerns over the applicability of the copyright system to software in a multilateral context under the auspices of the Universal Copyright Convention. If Brazil adopts a <u>sui</u> <u>generis</u> form of protection, we should explore USG options under available legislation.

Continue to emphasize the importance of copyright protection for software both because companies will be unwilling to jeopardize their software in Brazil if it is unprotected, and because Brazil will need protection if it is to develop software on its own.

3. Assessment for Progress

Prospects appear to be improving. GOB-backed legislation has not yet been introduced or passed and there are indications of an internal debate taking place on the merits of accepting the international consensus. 17

D. Unfair Competition Law

1. Issues

a. Adequacy of Legal Protection

Brazil's unfair competition law is the Industrial Property Code, which includes the patents and trademark laws and is administered by INPI. Special protection for well known marks and trade slogans is provided, with the requirement that the owner of the mark simultaneously request registration. Generally, <u>trade</u> <u>secrets, know-how and unpatented technology are not</u> considered protectible property rights.

Brazil's import licensing restrictions and high tariffs and taxes may effectively deny foreign suppliers their rights to protection from unfair competition. Although the Paris Convention requires national treatment, U.S. products subject to prohibitive import restrictions cannot meet the requirments of intellectual property protection laws. In a recent case, the trademark of a U.S. shoe manufacturer was compulsorily licensed to a competitor on the basis that it was not being worked during a period when imports were prohibited. Special representation was required to obtain reversal of this ruling by INPI. <u>Chemical manufacturers have also been hurt by the closing of the borders to final products or</u> their inputs when local production began.

2. Suggested Solution

Improved market access or relaxation of requirements for products subject to licensing restrictions.

3. Assessment for Progress

The GOB announced import liberalization measures in September 1984, but these have had little practical effect. In the case of the shoe manufacturer referred to above, the Ministry of Finance, which was responsible for the import restrictions, was approached. They blamed the problem on disorganization at INPI. A solution was eventually achieved through the combined intervention of government officials and private (Brazilian) businessmen. Solutions may be possible on a case-by-case basis, but INPI exercises a high degree of independence.

III. ITA Actions to Date

1/84-10/84 - Ongoing treatment of Monsanto patent violation case; issue raised at biannual meetings of Trade Subgroup and in bilateral meetings between government officials.

1/84-6/85 - Ongoing presentation of U.S. position on protection of computer software and U.S. concerns about Brazil's proposals to protect software outside of copyright; issue raised at bilateral meetings between government officials, biannual meetings of the bilateral Trade Subgroup, and Brazilian sponsored conference.

9/84-6/85 - Work with USTR and State to obtain action by INPI to reverse ruling on footwear trademark.

6/12/85 - Held Business/U.S. Government Roundtable and Corporate Briefing on Intellectual Property Protection in Brazil. Developed list of actions for private sector and USG to improve climate in Brazil.

Prepared by: WEarle/7-26-85/x5427/Wang #581

NEXT

INTELLECTUAL PROPERTY RIGHTS IN MALAYSIA

I. <u>Overview</u>

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Infringements of intellectual property rights in Malaysia are prevelant although to a lesser extent than in some other countries in Asia. Pirating and counterfeiting of videotapes, books, records, cassettes, cosmetics, pharmaceutical products and microcomputer software by Malaysian manufacturers are significant but retailers also import a large amount of counterfeited goods from countries such as Hong Kong, Singapore, and Indonesia. The major issue concerning U.S. companies was whether foreign works were protected under Malaysian copyright laws, but a landmark ruling by the Ipoh High Court in March 1985 clarified this issue. The High Court ruled that foreign works published within 30 days of first publication are entitled to copyright protection. Other issues still of concern are the insufficiently severe penalties for violations of the laws and the low priority the police give to copyright infringements. The GOM is aware of these problems and is taking steps to provide increased protection.

Numerous articles have appeared in the press supporting the call for improved copyrights and patent protection. Some of these articles highlight the U.S. Trade and Tariff Act of 1984 provisions for encouraging foreign government's to improve intellectual property protection.

Malaysia has four acts related to intellectual property rights: the Copyright Act of 1969, the Trade Description Act of 1972, the Trademark Act of 1976, and the Patent Act of 1983. The GOM has prepared a draft for a new copyright act. Some revisions are expected before it is promulgated in 1985. The Patent Act of 1983 has not been fully implemented. This may take a year or more. Malaysia is not a signatory to any of the international conventions on patents, trademarks, or copyrights.

The USG has been encouraging Malaysia to strengthen its intellectual property rights laws. The GOM has accepted and even sought out USG advice. In September 1984, Ralph Oman, Senior Counsel to the Senate Subcommittee on Patents, Copyrights, and Trademarks, went to Malaysia. He was well received by the GOM. Deputy Assistant Secretary for IEP Alexander Good visited Malaysia in September 1984. He met with Malaysian Deputy Minister Oo about intellectual property rights. DAS Good presented the Malaysians a draft model copyright law that was prepared by Ralph Oman. USDOC's Office of Pacific Basin, in conjunction with the Copyright Office_and PTO, organized a two-day copyright seminar in Kuala Lumpur January 29-30. II. Background

A. PATENTS

1. Issues

a. Adequacy of Legal Protection

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Malaysia adopted a new patent law in 1983 which was supposed to become effective in November 1984. The Patent Act of 1983 (Act 291) was published in the Official Gazette of December 1, 1983 but it remains a preliminary bill. According to government officials, amendments to the patent bill are likely to be introduced to Parliament in October. Regulations implementing the 1983 patent law have not been issued. These are expected to be introduced to Parliament in late 1985 or early 1986. Until the rules implementing the patent law are promulgated, no patent activity can be conducted under the new law. Mechanisms have not been established and fees have not been set. Malaysia is not currently a member of the Paris Convention but it plans to accede to the convention after the patent law is finalized.

The new patent system borrows heavily from the U.S. and various European patent systems. The two principal uses of a Malaysian patent are to promote licensing and to prevent infringement. Under the Patent Act of 1983, an invention is patentable if it is new, involves an inventive step, and is industrially applicable. Patents are valid for 15 years from the issue date. An invention is considered to involve an inventive step if such inventive step would not have been obvious to a person having ordinary skill in the art. This is just like the U.S. law. An invention is considered industrially applicable if it can be made or used in any kind of industry.

Like the European and Japanese patent systems, the new Malaysian system provides for a "utility innovation", which is like a "petty patent" or "utility model" in certain countries. The United States has no counterpart. The "utility innovation" need only be new, and need not involve an inventive step. The corresponding protection, however, is for only five years from the issue date. The "utility innovation" appears to confer on the owner the right to commercialize what is covered by the utility innovation. If this proves to be the case when regulations are ultimately promulgated, then these utility innovations could be valuable short term tools for the introduction of new products and processes into Malaysia.

Malaysia has added one feature to patent infringement litigation which have no counterpart in the United States. In Malaysia, under the new law, a court can render a judgement that the performance of a specific act would not constitute an infringement of the patent. In the United States, by contrast, it is not possible to get a hypothetical or advisory opinion as to whether or not infringement would occur if certain acts were to be performed.

Part IV Section 14 of the Patent Act of 1983 states that the following are not patentable:

- discoveries, scientific theories and mathematical methods;
- plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;
- schemes, rules or methods for doing business, performing purely mental acts or playing games;
- 4) methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body.
- 1. Licensing

Licensing in Malaysia is rather different from in the United States: In the United States, a license is a private contract between only two parties, the licensor and the licensee. But under the new law in Malaysia, licensing will be a triangular relationship between the two parties and the government. The patent owner and the intending patent user will first enter into a private contract which amounts to an agreement to license. Then the Malaysian government steps in, studies the intended license, and either approves or denies it on the basis of public policy. If it approves, then it is not the patent owner who grants the license, but rather the government. The governmental supervision of license agreements is a common feature of the patent systems of many developing countries. The Malaysian system, nonetheless, is unusual in that the government itself is the licensor.

The government considers applications according to two criteria: (1) whether there will be a transfer of technology involved; and (2) whether the royalties and technical fees are commensurate with the technology and know-how supplied. The review process normally takes three months.

The licensing period is normally five years, and renewal is subject to prior approval. Normally, a patent licensing agreement does not outlast the patent right for which it is granted. The licensee should be entitled to innovations or breakthroughs in licensed technology, including new patents. Adequate training should be provided by both the supplier and the local plant. Tie-in clauses are generally not permitted, and the government does not allow territorial restrictions on exports.

Licensing agreements (but not technical-assistance contracts) must be recorded to have legal effect. A licensee may sue in his own name against infringements.

The Ministry of Trade and Industry scrutinizes royalty and fee amounts. Preference is given to royalties of one to five percent based on net sales. Payments for technology can be made in lump sum, as a running royalty, or both.

As in many countries (excluding the United States), a patented invention which is not used or "worked" within three years can be the subject of a compulsary license. Application to the government is made by the intending licensee; and the license is granted on such terms as the government provides, unless the patentee. can advance a legitimate reason why the invention has not been worked. During Ralph Oman's visit to Malaysia in September 1984, the issue of compulsory licenses was raised by an attorney. Malaysia's new patent law appears to give the GOM the power to reassign the patent if the patent is not "worked" within three years. The legal counsel at the Ministry of Trade and Industry said that this was not the intent of the new patent law and any ambiguity would be clarified in future amendments. Part XV Section 84

of the Patent Act of 1983 allows the Government to authorize any department of its government or any individual in Malaysia to make, use and exercise any invention registered in Malaysia without liability to payment of compensation.

b. Adequacy of Enforcement

It is too early to tell how effective the new patent law will be Many Malaysian and foreign experts, including Ralph Oman, Senior Counsel to the Senate Subcommittee on Patents, Copyrights and Trademarks, think Malaysia's new patent law is detailed and provides good protection. The real question is how well it will be enforced.

c. Legal Sanctions

The legal sanctions have not yet been determined.

d. Fairness and Complexity of Registration

Under the proposed system, the registrar of patents and trademarks will examine patent applications for compliance with the law to assure that applications are complete and that formalities have been observed. The new system of examination is a major change from the previous system of re-registration of UK patents.

e. Participation in International Agreements

Malaysia does not belong to the Paris Convention but does plan to join. The GOM has sought WIPO and USG assistance to train personnel to use patent documents. A Malaysian patent examiner is participating in a month-long PTO training program in Washington, D.C. during July, 1985.

e. Local Private Sector Programs

The Asian Patent Attorneys Association (APAA) consisting 11 member countries has worked with the GOM. in developing the new patent law. Malaysia may establish its own Patent Attorneys' Association.

- 2. Suggested Solutions
- Continue to express USG interest in Malaysia's promulgating the regulations and fees as early as possible so the new patent law can become effective.
- Arrange for Malaysian participation in a U.S. Patent Office training program designed to teach one or a few patent officials how to use patent documents.

- Continue government to government discussion about our concerns over inadequate enforcement of the patent law and continue to offer technical assistance.
 - Encourage Malaysia to accede to the Paris Convention.
- 3. Assessment for Program

The GOM appears to be genuinely interested in providing good patent protection. It is likely to promulgate regulations in early 1985. The GOM will probably give consideration to any improvements we suggest in the new law.

B. TRADEMARKS

1. Issues

a. Adequacy of Legal Protection

Trademark registration is currently carried out under the Trademark Ordinance of 1950 in peninsular Malaysia, under Trademarks (Cop 142) in Sabah, and under Trademarks (Cap 62) in Sarawak.

New legislation governing trademarks was passed in 1976 but the government is still drafting regulations for enforcement. The new law supersedes previous ordinances, although existing registrations will continue to be protected. Industrial designs and models registered in the United Kingdom are automatically protected, but ignorance of the registration is a defense.

b. Adequacy of Enforcement

Infringement of trademark rights is prevalent, particularly in the cosmetic and pharmaceutical industries. Labels of well known foreign clothing are also favorite targets. The government periodically initiates drives to stop counterfeiting of recognized products, but its attempts have been generally unsuccessful and it does not seem particularly eager to solve the problem. Evidence of this is that enforcement regulations have still not been written for the trademark legislation passed in 1976.

c. Fairness and Complexity of Registration

Registration is initially valid for seven years and renewable for successive periods of 14 years. The first user is entitled to registration, which confers exclusive right of use. d. Participation in International Agreements

Malaysia is not a member of the Paris Convention.

e. Local Private Sector Programs

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2. Suggested Solutions

Encourage the GOM to enact enforcement regulations by reiterating our concern about the lack of existing trademark protection on every appropriate occasion. The "new" trademark legislation is meaningless until enforcement regulations are adopted.

- 3. Assessment for Progress
 - It is difficult to project when enforcement regulations to the trademark legislation will be adopted as it does not appear to be a priority item. It is unlikely any action will take place until the enforcement regulations for the Patent Act of 1983 are completed and the new copyright law under consideration is adopted.
- C. COPYRIGHTS
- 1. Issues
 - a. Adequacy of Legal Protection

Issues: The Ipoh High Court recently ruled that foreign works published in Malaysia within 30 days of first publication are entitled to copyright protection. The implications of this ruling reportedly go far beyond pirated video tapes of Cantonese soap operas (the subject of the court case). Apparently, under this ruling, any foreign work first published in Malaysia is entitled to copyright protection. Whether this applies to computer software, however, is still an unresolved issue. U.S. software dominates the market but many of the software packages sold in Malaysia are pirated copies of well known U.S. products. Software packages that sell for thousands of dollars in the U.S. can often be purchased in their pirated form for just a few dollars. We anticipate the new copyright law the GOM is working on will specifically address computer software.

Copyrights in Malaysia are protected by the Copyright Act of 1969 and the 1975 and 1979 amendments although a new copyright Act has been drafted and may be promulgated in 1985. Under existing law, copyright protection is extended only to Malaysian companies and individuals who are Malaysian citizens or permanent residents. Foreigners who do not reside in Malaysia and foreign companies that are not incorporated in Malaysia are not eligible for copyright protection. Their Malaysian agents and/or Malaysian subsidiaries, nonetheless, may qualify for copyright protection if they reproduce the work in Malaysia within 30 days of the date that the foreign work was first "published" overseas. Industry representatives complain that this is an unreasonably short time. They suggest a six-month grace period would be more practical.

Malaysian copyrights protect six types of work: 1) literary work, 2) musical works, 3) artistic works, 4) cinematographic films, 5) sound recordings, and 6) broadcasts. There is no category for computer software but it may fall under the "literary works".

The Ministry of Trade and Industry is in the midst of drafting a new copyright law. According to news reports, the new law will make substantial changes to existing laws, including a new section on enforcement, clearer provisions for video copyrights, protection for computer software, and heavier penalties against offenders. The new copyright law is expected to be introduced to Parliament in 1985.

In addition to copyright protection under the Copyright Act of 1969, the Trade Description Act (TDA) of 1972 also offers some protection. Under the TDA, it is a violation for anyone to apply a false trade description to goods.

During Ralph Oman's trip to Malaysia in September 1984, he suggested that since Malaysia's copyright law is very specific as to the six categories that are protected, software should be specifically protected as an additional category. Oman also suggested that the new copyright law should specifically address semiconductors, satellite broadcasts, and video tapes.

Oman subsequently sent a package of model amendments to the Malaysia copyright law which could afford protection to satellite transmissions, works of foreign origin, video cassettes recordings, and computer software. He also sent a copy of the U.S. Semiconductor Chip Protection Act of 1984. USDOC IEP/EAP, the Copyright Office and the Patent Office conducted a copyright seminar in Malaysia January 29-30, 1985.

b. Adequacy of Enforcement

Under the current act, enforcement is handled by the police. It is widely reported that the police do not pay adequate attention to copyright infringements. The draft of the new act gives enforcement authority to a special enforcement division within the Ministry of Trade and Industry to be headed by a controller of copyrights. This is expected to improve enforcement.

c. Legal Sanctions

Under the current Copyright Act, violaters can be fined up to a maximum of \$M10,000 (US\$ 4,200) for each infringing copy, up to a maximum of \$M100,000 (US\$42,000), or sentenced up to a maximum of five years, or both.

Between April 1982 to June 1984, the Ministry of Trade and Industry seized counterfeit goods worth US\$8.75 million. A total of 1,517 cases under the Trade Description Act during this period resulted in US\$381,000 in fines.

Violaters of the TDA can be fined a maximum of \$M100,000 (US\$42,000) or sentenced to a maximum of three years, or both.

d. Fairness and Complexity of Registration

Malaysia does not register copyrights. Copyright protection arises automatically and is conferred upon the author of the work (including corporate authorship).

e. Participation in International Agreements

Malaysia is not a signatory of the Berne Copyright Convention or of the Universal Copyright Convention.

f. Local Private Sector Programs

The national Artists' and Performers' Association and Malaysia's Computer Society are actively encouraging the government to update the copyright law and increase enforcement. 2. Suggested Solutions

- Amend the draft of the copyright law to include specific sections on computer software, satellite broadcasts, and more protection of video tapes.
 - Encourage Malaysia to sign one of the international copyright agreements and the Geneva Phonograms Convention.

Continue to work with the GOM following the copyright seminar on updating and then enforcing the new copyright law.

3. Assessment for Progress

The GOM appears to be genuinely interested in providing good copyright protection. It sees Malaysia as becoming the regional leader in software, for example, but it realizes this will not happen without adequate copyright protection. The GOM has been open to advice from foreign experts concerning the draft of the copyright law. It is unknown whether all of the suggestions will be incorporated into the law.

Even if the new law covers a wide range of categories, works originated outside of Malaysia will not be adequately protected unless Malaysia becomes a signatory to one of the two international agreements. The prospects for this do not seem bright in the near term. If enough pressure is brought to bear on the GOM by local and foreign businessmen and foreign governments, the GOM may decide to sign one of the international agreements.

D. Unfair Competition

The desk has no information at present.

III. ITA Action

3/83

OPB Director Severance and IPR specialist Lamb visited Malaysia to discuss the issue of IPR protection with Embassy staff and companies.

10/84

OPB staffer Linda Droker visited Malaysia in preparation for a copyright seminar; discussed copyright protection with Embassy staff, U.S. companies, and GOM officials.

9/84

DAS Alexander Good met with Malaysian Deputy Minister of Trade and Industry Oo Gin Sun. He presented the draft model copyright law prepared by Ralph Oman and discussed intellectual property right issues during this meeting.

1/85

Copyright seminar sponsored by OPB, PTO and the Copyright Office. FCS is coordinating this effort in Malaysia.

NEXT

INTELLECTUAL PROPERTY RIGHTS IN INDONESIA

I. Overview

The problem of intellectual property rights protection in Indonesia is potentially a large one. A lack of good information makes it difficult for the desk to estimate the dimensions of the situation, or to rank-order the specific problems. Counterfeiting in Indonesia appears to focus mainly on garments (counterfeiting of blue jeans seems to be the major problem), accessories, and some chemical products, including pharmaceuticals. Copyright problems exist in the areas of publishing, and audio- and videocassettes. Computer software piracy has not been a significant problem, but could become so in the future. Some of the counterfeit products available in Indonesia have been imported from other parts of the region, but it also exports items such as jeans and audiocassettes to other countries in the region.

The legal system is relatively undeveloped. (There is no patent law, for example.) In the past, Indonesian law was based on Dutch law. However, the government is gradually eliminating many Dutch statutes and replacing them with Indonesian laws. An additional problem with obtaining legal redress is corruption throughout the government, including the police and courts.

- II. Background
 - A. Patents
 - 1. Issues

a. Adequacy of Legal Protection

Indonesia currently has no patent law. A draft law was tabled in the Indonesian parliament in mid-1983 and has since been redrafted and remains in committee. Its provisions largely follow those of the WIPO model for developing countries. Until enactment of the law, patent applications will continue to be accepted under a 1953 Department of Justice decree. (Provisional applications have been accepted in this manner since 1963. There are over 8,000 applications now on file.) Such provisional applications will not be acted upon nor will they be published or made available for public inspection prior to enactment of the patent law. A patent application filed under this decree will create for the applicant a priority claim under the Paris Union Convention over applications submitted at a later date. The Embassy in Jakarta has suggested that, even when the patent law is adopted, it is unlikely to cover pharmaceuticals, since most pharmaceutical companies entered the Indonesian market before the GOI began accepting provisional patent applications. It is not clear whether pharmaceutical companies would be forbidden to apply for patents for new products.

There is no law covering industrial designs or models.

The desk has little information as to the specific impact on U.S. companies of the lack of a patent law, other than that some companies have cited it as a problem.

In May 1983, the GOI Director of Patents Supjan Suradimadja visited the U.S. to meet with PTO officials. At that time the USG offered, and later delivered, copies of all U.S. patent documents from 1970-83. The purpose of this gift was to establish a reference base for the GOI for such time as the patent law is adopted. However, it is not clear whether the documents are currently being put to any use.

According to a U.S. company, government guidelines for permitted royalties can be stringent: for agrochemicals, a maximum of 0.5 percent on net ex factory sales for no more than 10 years; for pharmaceuticals, 5 percent for up to 10 years; and for textiles, 3.5 percent for up to five years.

b. Adequacy of Enforcement and Legal Sanctions

N/A

c. Fairness and Complexity of Registration Procedures

N/A

d. Participation in International Agreements

Indonesia is a member of the Paris Convention.

e. Local Private Sector Programs

The desk is unaware of any such programs.

2. Suggested Solutions

Pass a patent law, preferably covering chemical compounds, and incuding designs and models.

Attempt to persuade GOI officials of the benefits in terms of foreign investment and technology transfer of adequate patent protection. Possibly the USG could undertake further educational efforts, such as seminars (see II.C.2), or government-private sector delegations. However, such delegations should also visit other countries in the region, since Indonesia by itself is still a smaller scale problem.

Raise the issue of patent and other intellectual property rights protection in consultations under the Memorandum of Understanding on Investment.

3. Assessment for Progress

The Embassy can give no estimate as to when the patent law might be passed. Interagency disagreements over whether to include chemical compounds are evidently part of the problem.

The GOI understands that better protection for intellectual property rights is important for increasing foreign investment in Indonesia. At the same time, many officials take a highly nationalistic view, believing that protection for foreigners should have a lower priority than encouraging local entrepreneurs or saving foreign exchange. These domestic political concerns, combined with corruption in the legal system, make it unlikely that significant improvements will be made in the near term.

B. Trademarks

1. Issues

a. Adequacy of Legal Protection

Trademark registrations are granted under the Trade Name and Trademark Act (No. 21 of 1961) for 10 years from date of registration and may be extended for like periods.

The Trademark Law does not currently cover the issue of the right of use of trademarks by licensees. As of March 1983, a provision on licensing was being drafted as an amendment to the law. In 1982 a senior GOI official proposed a ban on the use of foreign trademarks and brand names and a greater use of Indonesian trademarks. The intent behind the proposal was both nationalistic and economic (it would reduce royalty payments). There continues to be pressure within the GOI to phase in local trademarks while phasing out foreign marks.

b. Adequacy of Enforcement and Legal Sanctions

1. Enforcement

Despite a 1972 Supreme Court ruling that the intent of the Trademark Law is to protect the public from inferior goods, enforcement is lax. Police raids on suspected counterfeiters are made only if requested by the trademark holder, but police do not regard counterfeiting as a high priority. In the past, the Minister of Manpower has stated that he did not want raids to result in the unemployment of Indonesian citizens. The desk has no information as to the impact of this statement.

2. Legal Sanctions

The penalty for counterfeiting convictions is a fine; no prison sentences are given. The desk has no information as to the amount of fines or as to the likelihood of convictions.

Court injunctions have been obtained against counterfeiters. In the case of one U.S. company, a favorable decision was obtained from the Supreme Court itself, although USG pressure may have been the determining factor.

Corruption in the court system is know to be a problem. Besides bribery of judges, <u>Business International</u> reported in 1983 that defendants sometimes buy or steal case documents from the court clerk following a guilty verdict; this effectively eliminates all record of the case.

c. Fairness and Complexity of Registration Procedures

The first bona fide user of a mark for a class of goods is entitled to the trademark registration for that class. In absence of proof to the contrary, the first applicant for registration is considered as having been the first to make use of the mark (rather than having been the first to register the mark), provided he uses the mark within z 6 months after the registration and at least once every 3 years thereafter for the goods covered thereby. There is no prior home registration requirement for U.S. nationals seeking to register a trademark in Indonesia. Interested U.S. applicants must file through a resident agent or attorney in Indonesia. A 1972 Supreme Court case established that joint ventures are entitled to use the foreign parent's trademarks. Applications are examined and, if found acceptable, registration is granted. There is no provision for opposition before the trademarks office under Indonesian law. However, once a mark is registered, a party who believes the registration violates his rights may file a petition to cancel the registration with the District Court of Jakarta. Such a petition must be filed within 9 months of publication of the registration.

Conscious of the possibility that local bodies might try to reserve use of internationally known trademarks, the Indonesian authorities are taking steps to check trademark applications against international listings prior to registration.

d. Participation in International Agreements

See II.A.1.d.

e. Local Private Sector Programs

See II.A.l.e.

2. Suggested Solutions

The USG could possibly use a new MTN round and the GSP review process to encourage improvement in the trademark protection situation. Through these processes, we want to encourage the GOI to:

Increase the penalties for infringement

Increase the priority police give to making raids.

- (See also second point under II:A.2.)

3. Assessment for Progress

- (See II.A.3.)

- C. Copyrights
- 1. Issues
- a. Adequacy of Legal Protection

Copyrights are covered by Act. No. 6 of April 12, 1982, which is based on the 1971 Berne provision for developing countries. This Act replaces the previous law, the Netherlands Copyright Act of 1912. Under the Dutch law, copyright protection for an author's work was granted for his/her life and 50 years after his/her death. U.S. worksare not eligible for copyright protection unless they are first published in Indonesia (works published elsewhere and then published in Indonesia within 30 days are <u>not</u> eligible). Corruption, infrastructural inefficiences, and legal restrictions on doing business have all interacted with copyright problems to keep U.S. copyright industries out of the country.

Chinese characters are under a total ban. Books and magazines printed in Indonesia must be in the Indonesian language, although publications in other languages can be imported.

b. Adequacy of Enforcement and Legal Sanctions

While registration of books for copyright protection is relatively easy, enforcement of protection for published materials, particularly translations of foreign books, videotapes, and cassette tapes, is lax. The minimum fine for copyright infringement is rupiah 500,000 (\$500) and 6 months imprisonment; the maximum is rupiah 5 million (\$5,000) and 3 years imprisonment.

c. Fairness and Complexity of Registration Procedures

Other than the above, the desk has no information on this subject.

d. Participation in International Agreements

Under the Dutch law, the Netherlands' membership in the Berne and the Universal Copyright Conventions covered Indonesia. Indonesia withdrew from the Conventions during the early 1960s. It has expressed interest only in a bilateral copyright relationship with Malaysia. e. Local Private Sector Programs

The National Law Development Agency of the Department of Justice is interested in improved copyright protection.

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2. Suggested Solutions

In the short term, the USG may have to emphasize the need to establish direct copyright relations with Indonesia, regardless of the uncertainties of Indonesian law and chaos in the marketplace itself. Non-eligibility of U.S. works is the threshold problem and leverage to argue for improvement of local law can come with copyright treaty relations. The USG should explore GOI willingness to establish bilateral copyright relations. Following the establishment of such relations, it may be possible to encourage the GOI to:

- Join the Berne or Universal Copyright Conventions.
 Revise its copyright law to protect computer software and satellite broadcasts.
- (Also see second point under II.A.2.) Regarding educational efforts, ITA, PTO, and the Copyright Office organized a seminar on copyright protection in Indonesia, Malaysia, and Thailand in January-February 1985. The attendees at the Indonesia seminar appeared to think that Indonesia should be more economically developed before giving attention to copyright protection for foreigners.
- 3. Assessment for Progress
- See II.A.3.
- D. Unfair Competition
- 1. Issues
 - a. Adequacy of Legal Protection

The desk is unaware of whether an unfair competition law exists in Indonesia. Trade dress problems do affect U.S. companies, especially in the area of consumer product trademarks and some service marks.

b. Adequacy of Enforcement and Legal Sanctions

N/A

c. Fairness and Complexity of Registration

N/A

d. Participation in International Agreements

See II.A.1.d.

e. Local Private Sector Programs

See II:A.1.e.

2. Suggested Solutions

 Remind the GOI of its obligation under the Paris Convention to assure other signatory countries of protection against unfair competition.
 Assessment for Progress

See II.A.3.

III. ITA and PTO Actions to Date

- 5/83 PTO and OPB hosted Washington visit of Indonesian Patent Director Supjan Suradimadja
- 12/83 PTO gift of U.S. patent documents delivered to GOI
- 6/83 Deputy Patent Commissioner Donald Quigg visited Indonesia
- 9/84 OPB staffer Linda Droker visited Indonesia to begin preparations for copyright seminar
- 2/4-

5/85 USDOC Copyright Seminar

- 5/24/85 Issue of IPR protection raised with GOI investment officials during first meeting of Joint Investment Commission in Jakarta.
- 7/12/85 IPR, including need for passage of patent law with chemical compound coverage, raised at second JIC meeting; paper on pharmaceuticals industry problems passed to GOI.