ORAL

(1) I am here as a private citizen. I do not wish to use my 15 minutes identifying my credentials, so I attached my C.V. to my remarks. ~~The problem of~~ Drug pricing is a serious problem that effects everyone and needs to be addressed. ~~This is not the proper forum~~ But this is not the forum for its resolution today. I am here to defend Bayh-Dole and not debate pharmaceutics.

~~The central~~ The basis for the petition being discussed is the allegation that the march-in rights of Bayh-Dole give NIH the authority to determine whether the price of a drug is unreasonable and if so give NIH the ~~right to require~~ ~~compulsory license generic drug manufacturers. Requires the~~ right to grant multiple licenses. ~~This is not correct.~~

~~The petitioners misstate~~ To support this the petition maintains that the entire government investment in health research and development demands this interpretation of the march-in provisions, and that the term "reasonable

(2)

terms in Sec. 304A of the Act, in its ordinary context, must be interpreted to mean "Reasonable prices". None of this is supported by a correct reading of the Act and its legislative history.

First, only a very small portion of the government's health R+D investment is directed to drug research. Most is directed to grant funding to investigate the frontiers of the life sciences. The Act is directed to those individual situations where an incentive is needed to develop a composition of matter with no proven utility or safety.

The Act recognized that the government does not develop drugs and that the private investment necessary to prove utility and safety normally exceeds by many multiples the government funding that produced these inventions.

(2)

makes clear
The Act's legislative history ~~makes~~
~~clear~~ that the public equity in
~~the lowest-cost~~ funding ~~for~~ the ~~most~~
~~quickly~~ ~~drugs~~ will be ~~rewarded~~ fully
by producing drugs that ~~extended~~
improve and extend the lives of
millions of their countrymen. ~~that~~
would otherwise ~~never be available~~ not
be available.

The Act's legislative history makes
clear that the public

(4)

With regard to the ~~petitions~~ petitioners argument that "nonprofit teams" must include "nonprofit grantees" as a simple reading of Sec. 203 without regard to any legislative history shows such interpretation to be ~~absolutely~~ completely incorrect.

Section 203(a) only applies to contractors and assignees as defined by the Act. Licensees are not included by design. ~~Because~~ ~~they~~ as the next two sections apply to contractors, assignees and licensees and the last section applies only to licensees.

In 1980, it was clear that most of the ~~(contractors of Sec. 203)~~ small business and NON-profit contractors of 203 ~~would not participate~~ ~~in~~ ~~new~~ ~~development~~ by the drug industry under ~~any~~ only could be developed under licenses with the drug industry.

In this situation, the contractors did not set the prices of the drugs ultimately marketed under their licenses. In fact there is nothing in the Act to require them to do so ~~and apply reason for them to get out from under an initiative which would be~~ inconsistent with the incentive to gain industry cooperation. The sales price is set only by the licensee who is indicated as not subject to 203A.

Since no party subject to sec. 203A sets market price prices it is clear that there is no reason whatever to assume that "reasonable terms" ~~include~~ must include "a reasonable price".

Well then how can "reasonable terms" be more specifically ~~interpreted~~ interpreted in the context of sec. 203A in 1980? That's easy. ~~Requiring "reasonable terms" is~~ Requiring "reasonable terms" is a responsibility ~~of the contractors under 203A~~ that the contractors of sec. 203A must ~~pursue~~

(6)

~~What~~ answer to when necessary ~~necessary~~ a license with a prospective licensee.

But don't act as if it is a stretch to say this is not making the product available to the public on reasonable.

I don't think you should act as if your petition

Explain ~~Unlikely~~ safely

Since a lawful agreement would

Norman J. Latker

Statement Before NIH On
Essential Inventions Petition Regarding Norvir

May 25, 2004

Hello. I'm Norm Latker, and I'm here to address the petition sponsored by Mr. James Love of Essential Inventions, which asks NIH to end the exclusive title held by Abbott Laboratories for the AIDS drug Norvir.

I thank you for the opportunity to address this issue today.

While I am sympathetic to the efforts of Mr. Love, which I believe are motivated by a desire to enhance the quality of life for the millions of Americans living with AIDS, I must oppose his petition, which, if successful, would undermine the integrity of the Bayh-Dole Act, which I helped to draft back in the 1970s.

Although there was spirited opposition to Bayh-Dole when it was brought before Congress in 1980, a broad political consensus was ultimately built around the notion that market forces would do a far better job of disseminating government-sponsored inventions than bureaucracies ever could.

The Act has been enormously successful. As the Economist Magazine put it recently, it is "the most inspired piece of legislation to be enacted in America over the past half-century."

That may sound like hyperbole, but the impact of the Act has indeed been astounding—and overwhelmingly positive.

It has fostered a potent four-way partnership between researchers, their institutions, government and industry. That partnership has evolved into the most powerful engine of practical innovation in the world, producing innumerable advances that have extended life, improved its quality and reduced suffering for hundreds of millions of people.

Of course, the law isn't perfect. No law is. There have been changes in the three decades since Bayh-Dole's passage—changes that no one could have predicted. But overall it has stood the test of time.

While I feel I can provide some perspective on the Act, there is very little I can say with authority on the underlying issues that have prompted Mr. Love's petition.

Frankly, there are a number of things that I simply do not know.

For example, I don't know how Abbott Laboratories reached its decision to raise the price of Norvir. I don't know whether it was based on legitimate business issues, or as AIDS activists allege, on simple corporate greed.

Nor can I pretend to know what impact the price hike will have on those who need the drug to stay healthy, or on the healthcare finance system. I do not know if some people who need Norvir will now not have access to it. I don't know whether Abbott's promise to provide the drug for free to those who cannot afford it should be taken at face value.

It is worth noting that Senator John McCain has called on the Federal Trade Commission to investigate Abbott Laboratories for possible abuse of its monopoly power with respect to Norvir. Attorneys General in Illinois and New York are also looking into the matter. Again, I do not know precisely what criteria these organs of government might use to determine whether corrective action is warranted.

But I do know this: the Bayh-Dole Act is not an arbiter of healthcare policy or drug pricing, and was never intended to be.

Bayh-Dole defines critically important aspects of intellectual property law, while ensuring that viable government-sponsored research does not go to waste.

It is decidedly ill-suited for any other purpose.

Simply put, the legal philosophy of Bayh-Dole is this: if the government accords broad marketplace prerogatives to the developers of government-funded inventions, such inventions are far more likely to be developed and disseminated to the public.

The law holds that intellectual property rights should be accorded in full to the innovators, rather than to the government agency that financed their research, and that developers should be free to leverage their property rights to their advantage in the market place as intended by the patent system.

There were a few conditions placed on this freedom—conditions which are now the subject of dispute. In layman's terms, the conditions provided that:

a) Reasonable efforts were required to develop the inventions to practical application, and made readily available to society;

b) The inventions should not be used in such a way that might threaten public health;

c) If an invention were subject to a federal order of some kind, the developer must comply with that order; and

d) The marketed invention should be made within the United States.

These conditions were translated into the legal language found in section 203 of the Act—what we now refer to as the "march-in" clauses, because they give the government the power to "march-in" and reassign intellectual property rights. These were conceived as extraordinary measures to be used only when there was overwhelming evidence to show that the public resources invested into an innovation were being wasted or abused.

Obviously, Abbott Laboratories has been enormously successful in bringing the benefits of Norvir to the public at large. The drug may be expensive—perhaps intolerably expensive, given the critical importance it

holds for people with AIDS. But by the criteria established by Bayh-Dole, Abbott has complied with the law.

Mr. Love would of course disagree, both with my interpretation of the march-in clauses and my belief that Abbott has not broken the law.

His petition asserts that Bayh-Dole invests NIH with the authority to determine whether the price of Norvir is too high and, if so, to terminate the exclusivity of Abbott's property rights.

The petition points out that one march-in clause, section 203a, specifies that the invention in question must be made available on "reasonable terms", which the authors interpret to mean "reasonable prices".

None of this is supported by a correct reading of the Act and its legislative history.

In fact, if the drafters of Bayh-Dole had intended such an interpretation, we would have inserted specific criteria into the law to enable NIH—or any government funding agency —to assess what a reasonable price might be. No such criteria are found, because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Nor did we envision that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information. If we had foreseen such a process, the Act would have contained enabling language specifically empowering it.

It must be admitted that the law is written in the arcane legalese of the period, and many sections are quite easy to misinterpret unless armed with the correct definitions.

Let me provide some of those definitions now.

The Bayh-Dole Act refers to three key entities involved in the government-sponsored research and subsequent development of an invention.

1) Contractors: These are the organizations that originally used government research funds to make fundamental discoveries

2) Licensees: These are the entities that acquire a license to an invention, develop it and bring it to the marketplace. They pay royalties to the contractor. And bear risk… In the fields of human health and life sciences, these are usually drug companies.

3) Assignees: These are defined by the Act as non-profit patent management organizations, which at the time brokered the license agreements between the contractor and the licensee. Their role has been marginalized in recent years as universities and research institutes have taken on the role themselves.

When reading the march-in clauses, it is important to understand that Section 203a *only* applies to contractors—that is, the original researchers – and assignees.

Section 203a does *not* apply to licensees.

This was not an accidental omission. That licensees are consciously excluded from 203a is obvious, because the next three sections -203b--d explicitly apply to all three entities: contractors, assignees and licensees.

Back in 1980, it was clear that most health inventions could only be practically developed under licenses with the drug industry. Bayh-Dole granted the property rights to the contractor, who would then negotiate a license agreement with the licensee. Of course, drug pricing played *no role* in these negotiations. Pricing a drug which has not yet been tested, approved and marketed is, of course, impossible.

As the phrase "reasonable terms" found in 203a applies to *contractors*, and not to *licensees*, it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices. Further, they are not required to do so under the defined contractor obligations under the Act.

The phrase clearly refers to the terms of the agreement between the contractor and the licensee.

Bayh-Dole wants government-sponsored inventions moved to the marketplace. Towards that end, it obligates the contractor to transfer the invention to the licensee without demanding exorbitant, or unreasonable, *royalties.*

The ultimate price of the drug to be developed had nothing at all to do with section 203a or the contractor's defined obligations under sec. 202c. Pricing was —and is—left to the discretion of the licensee. It is the licensee, after all, who bears all the risks of developing the innovations—the clinical trials, the FDA approval procedures, the vagaries of the marketplace. They do so because they know that Bayh-Dole guarantees them exclusive rights over the invention.

After explaining all that, I must now point out that Norvir has *never* been licensed, and that Abbott Laboratories is *not* a licensee. It is, in fact, a contractor who obtained title to its invention directly through a contract with NIH.

Again, when the law was written, we thought that in most cases, a contractor would be an academic, research institute or small business that would not have the resources to develop and market the invention on their own. Bayh-Dole therefore emphasizes the licensing process, as is abundantly evident throughout the Act and its implementing regulations.

Abbott Laboratories, as it happens, had no need to license its invention. It had title to the invention and the resources to bring it to the market without any assistance.

This exposes a minor ambiguity in Bayh-Dole. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as a requirement of the contractor under its defined obligations.

In other words, we cannot spontaneously reinterpret 203a to mean that when a contractor brings a drug to market itself, it must price the drug "reasonably". "Reasonable terms" could not mean one thing for a licensee, and another for a contractor, unless the law contained specific language defining these meanings.

The intent of 203a is obvious enough, even if it fails to specifically address the case at hand.

In closing, I'd like to return briefly to the broader issues that have prompted Mr. Love's petition.

It must be plainly understood that medical access problems in the United States stem *not* from the research and development regime, but from the way healthcare entitlements are ascribed and healthcare resources are distributed.

I confess that I am no fan of price controls, because I believe that they could stifle innovation and drastically reduce the amount of money the drug industry pumps into pharmaceutical research every year. Contrary to what has been published in recent weeks, only a very small portion of the government health research and development funds are channeled directly into drug research and clinical studies. Most is used to sponsor investigations into the life sciences.

It is in fact the private sector that ponies up the resources to develop, test, obtain approval for, and market new drugs. It is an undeniable responsibility of government to create and maintain incentives for these investments, because there is no way the government could manage the job on its own.

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is

why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

That said, the public has an interest in affordable healthcare. I think there are many ways that might be achieved without resorting to outright price controls. State governments, for example, are themselves major purchasers of drugs, and could, through clever use of their market power, help keep prices down.

If a political consensus were to emerge that drug prices need to be controlled by the government, the only legal and appropriate means of instituting such controls would be through a full-fledged legislative process, tested by the courts and administered through empowered organs of government.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into an administrative mechanism to control drug prices would have intolerable consequences for innovation, drug development and healthcare in this country.

A sober reading of the Bayh-Dole Act will leave no doubt that retail drug pricing has nothing to do with the march-in provisions of the Act.

Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Report to Congress on

Affordability of Inventions and Products

July 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Affordability of Inventions and Products

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Affordability of Inventions and Products

Executive Summary

In Section 218 of the Conference Report on H.R. 2673, Consolidated Appropriations Act 2004, the Committee on Appropriations requested that the National Institutes of Health (NIH) prepare and submit a report addressing the affordability of inventions and products developed with Federal funds. The following is submitted in response to the request.

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. The goals of the agency are as follows: 1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; 2) develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease; 3) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

The NIH recognizes the importance of finding an equitable solution to the issue of affordability of inventions and products. However, any role it might assume in the affordability discourse would, of necessity, be limited by the fact that the Federal Government has rights in only a very small number of commercialized products and inventions. It is also important to consider the effect of taking any actions that might result in fewer new products that might improve public health reaching the market.

The NIH contributes to the affordability of inventions and products by conducting and funding medical research that may eventually lead to the development of new drugs and devices and, ultimately, significant improvements in human health and the quality of life.

Introduction

In Section 218 of the Conference Report on H.R. 2673, Consolidated Appropriations Act 2004, the Committee on Appropriations stated:

SEC. 218. Not later than 90 days after the date of enactment of this Act, the Director of the National Institutes of Health shall submit to the appropriate committees of Congress a report that shall--

(1) Contain the recommendations of the Director concerning the role of the National Institutes of Health in promoting the affordability of inventions and products developed with Federal funds; and

(2) Specify whether any circumstances exist to prevent the Director from promoting the affordability of inventions and products developed with Federal funds.

This report addresses the issues contained in the legislative committee request. While the report requests the NIH Director to address the role of the NIH in promoting the affordability of inventions and products developed with Federal funds, we are, of course, only in a position to address inventions funded by our agency.

Recommendations of the NIH Director Regarding the Affordability of Products Made Using Federally Funded Inventions

The NIH Director believes that the optimal approach that the NIH can legitimately pursue in promoting the affordability of inventions and products developed with NIH funds is through the conduct and support of outstanding health-related research relevant to the American people. The NIH was established with the mission of science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. In those instances when such research leads to a novel technology, it is the role of the NIH and recipients of NIH funds to disseminate the research findings and, as appropriate, pursue further development to bring technologies to practical application to benefit the public.

The NIH has a role to play in the early-stage development of technologies that are later brought to market by its licensees or commercial collaborators. The final product, whether it is a therapeutic, a diagnostic, or a medical device, is often the result of a host of discoveries contributed over the years by numerous university, government, or commercial laboratories. The NIH typically contributes to the understanding of basic and clinical biology (such as the pathogenesis of a disease, the immunological or genetic processes associated with a disease, etc.) that helps in guiding translational research toward producing a cure or therapy. NIH investigators often create research tools that are used in the path to drug discovery by private industry.

Even in those few cases in which an NIH-invented technology is an identifiable part of a final product, the invention would typically be one of numerous components that would go into building that product. Such invention components may range from a novel method of administering the prescription drug to an active ingredient combined with other compounds to make the final drug. A good analogy would be that of an automobile, where different components are invented and manufactured by a variety of entities. Just as the provider of any one component of an automobile cannot dictate the cost of the final vehicle, the provider of a single technology in the development of a therapeutic drug cannot dictate the final cost of the drug.

The research supported and conducted by the NIH is sometimes mischaracterized as necessarily resulting in the commercialization of drug products. In truth, much of NIH funding supports the exploration of fundamental biological mechanisms that would otherwise not be pursued due to the lack of market incentives. Such research can lead to early-stage findings and provide clues that may eventually lead to medical advancements for diseases for which existing methods of therapy are nonexistent, inefficient, or suitable only for a select population. For example, original research on hormones conducted in the 1960s uncovered the mechanism by which a specific protein, the G-protein, allowed cells to signal each other. Building upon those early studies, researchers discovered that bacterial and viral agents cause disease by acting on G-proteins and, as a result, G-proteins are now the target of 65 percent of all prescription drugs invented primarily, if not entirely, by the commercial sector.

Any possible NIH role in the affordability debate would be limited strictly to the small fraction of commercialized products developed with Federal funds. The July 2003 GAO Report to Congressional Committees entitled "Technology Transfer Agencies' Rights to Federally Sponsored Biomedical Inventions" found that of the top 100 pharmaceuticals procured by the Department of Veterans Affairs in fiscal year 2001, only five implicated Government rights. Additionally, of the top 100 pharmaceuticals dispensed by the Department of Defense between July 1, 2001 and June 30, 2002, only three had active Government rights.

About one-third of the NIH grants awarded support a robust clinical research program. The NIH Roadmap for medical research in the 21st century, announced in September 2003 (http://nihroadmap.nih.gov/), includes plans for enhancing the manner in which NIH conducts and supports research leading to improvements in public health. For example, the plan for "Re-engineering the Clinical Research Enterprise" is designed to build a stronger clinical research infrastructure that facilitates the translation of basic research to clinical application, including the development of technologies to improve the assessment of clinical outcomes. Another goal is to work within the Federal system of clinical research oversight to promote coordination of policies, requirements, and procedures concerning clinical research and, where appropriate, to help create streamlined approaches. (Also see Dr. Zerhouni's testimony to the Subcommittee on Health of the Committee on

Energy and Commerce, House of Representatives, March 25, 2004; and Zerhouni, E.: The NIH Roadmap, *Science*, Vol. 302, pp. 64, 72, October 3, 2003). Other efforts include collaborations between the NIH and the Food and Drug Administration to facilitate the development and use of better cancer treatments including efforts to reduce the time it takes for promising new drugs to be reviewed for testing in clinical trials (see the National Cancer Institute's press release of November 12, 2003, http://www.nci.nih.gov/newscenter/pressreleases/FriendsFDANCI).

Overall improvements in efficiency and time and reduction in risk to industry in bringing drugs to the marketplace should result in not only new and better drugs for the American public but also permit industry to price the drugs lower than they would otherwise.

Circumstances Preventing the Director from Promoting the Affordability of Products Developed Using Federally Funded Inventions

The Bayh-Dole Act (Public Law 96-517) and the Stevenson-Wydler Technology Innovation Act (Public Law 96-480), as amended by the Federal Technology Transfer Act of 1986, provide the statutory framework and authority for federally funded technology transfer operations. The former addressed the barriers to the development and commercialization of federally funded inventions, while the latter established the basic Federal technology policies. Neither provided the NIH with the legislative authority to specify commercialization terms in the agreements of its grantees and contractors.

The cost of prescription drugs is a legitimate public concern that exists whether or not a drug was developed from a technology arising from federally funded research. NIH, however, has neither the mandate nor the authority to be the arbiter of drug affordability.

It is the mission of the NIH to advance research with the goal of improving public health (42 U.S.C. § 281). The NIH focuses on support of research, training, and health information dissemination and other programs associated with a particular NIH Institute's specific mission (42 U.S.C. § 285), consistent with Department of Health and Human Services authority for conducting research and investigations (42 U.S.C. § 241). NIH's legislative authority, however, does not extend to the affordability of products (42 U.S.C. §§ 281-282).

Central to both Stevenson-Wydler and Bayh-Dole was the concept of using the patent system as an incentive to private industry to participate in the further research and development needed to bring early-stage Federal innovations to practical application in the marketplace. Responsibility for managing intellectual property rights, as well as the rewards derived from their commercialization, was provided to funding recipients under Bayh-Dole.

Bayh-Dole permits only limited oversight of technology transfer operations by the funding agency. For example, the NIH must approve assignment of ownership to third parties or foreign manufacture of products for use in the United States (35 U.S.C. § 202(c)(7) and 35 U.S.C. § 204, respectively). Should a critical public health emergency arise, the NIH may require mandatory licensing or sublicensing if it determines that a technology is not being moved to practical application (35 U.S.C. § 203). Bayh-Dole, however, does not provide authority for the NIH to control the pricing of products resulting from inventions made by funding recipients.

Affordability of health inventions and products is a relative term involving numerous interactive market forces including accessibility, intellectual property rights, and insurance reimbursement options. Affordability is a function of the individual person's ability to bear the cost of a particular drug. Many companies, therefore, have indigent patient programs to supply drugs to some patients on a discounted or no cost basis, thereby making them affordable to those patients.

In fact, the issue of drug affordability is often a matter of access. Access to drugs and vaccines, etc., may be influenced by a number of factors. For example, generic versions of drugs that have passed the term of patent protection are almost always cheaper than the original. Furthermore, drugs purchased from wholesalers are less expensive than those from retailers and distributors. Adding to this complexity are the vagaries operative in reimbursement and insurance mechanisms that may affect the accessibility and, hence, the perception of affordability of a therapy.

A case in point is that of Synagis® used to treat Respiratory Syncytial Virus (RSV) infections, particularly in children (http://ott.od.nih.gov/newpages/techdev.pdf). This therapeutic was developed in part from an NIH technology. Prior to the arrival of this therapeutic in the market, the most effective treatment available against RSV required a hospital stay. Synagis® now provides a solution in the doctor's office at a total cost much less than the cost for hospitalization. The actual out-of-pocket cost to the patient in obtaining this in-house treatment, however, is higher than the cost of hospitalization. This is due to insurance reimbursement policies that require the patient to pay a portion of the total cost for this in-office treatment, while little or no cost is incurred by the patient in the case of hospitalization. As this example illustrates, the issues surrounding the affordability of drugs and therapeutics are very complex and beyond the scope of the authority of the NIH.

In the July 2001 NIH report entitled "A Plan to Ensure Taxpayers' Interests Are Protected," the issue of "reasonable pricing" of federally funded inventions was discussed in depth. As part of the evaluation done for the report, a special panel was convened that included scientists and administrators from government, industry, academia, and patient advocacy groups. The panel concluded that the descending hierarchy of importance of return on public investment in NIH research should be fostering scientific discoveries, rapid development of technologies as

effective therapeutics, accessibility of resulting products to patients and, lastly, royalties. The report also described the "chilling effect" that the imposition of requirements for price controls had on collaborations between NIH and industry and came to the conclusion that such price controls were, in fact, contrary to the tenets of the Bayh-Dole Act.

Conclusion

Although establishing standards for the affordability of drugs and therapies is beyond the agency's mission or authority, the NIH contributes to affordability through research that leads to the development of a wider selection of drugs or new drugs, where no drugs were available. More alternatives can translate into more choices for the public, greater market competition, affordability and, ultimately, overall return to society by the improvement of the quality of life. Thus, as long as NIH continues to focus on its core mandate, namely conducting and funding broad-based research that could lead to the development of new drugs and therapies in the future, we believe that the NIH is acting as a responsible partner in the national enterprise to improve the quality of life for the public and to make drugs more affordable.

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None of this is supported by a correct reading of the Act and its legislative history.

In fact, if the drafters of Bayh-Dole had intended such an interpretation, we would have inserted specific criteria into the law to enable NIH—or any government funding agency —to assess what a reasonable price might be. No such criteria are found, because controlling patent rights on the basis of price was antithetical to what the drafters had in mind.

Nor did we envision that the law could authorize government funding agencies to compel private entities to divulge internal accounts or pricing information. If we had foreseen such a process, the Act would have contained enabling language specifically empowering it.

It must be admitted that the law is written in the arcane legalese of the period, and many sections are quite easy to misinterpret unless armed with the correct definitions.

Let me provide some of those definitions now.

The Bayh-Dole Act refers to three key entities involved in the government-sponsored research and subsequent development of an invention.

1) Contractors: These are the organizations that originally used government research funds to make fundamental discoveries

2) Licensees: These are the entities that acquire a license to an invention, develop it and bring it to the marketplace. They pay royalties to the contractor. And bear risk... In the fields of human health and life sciences, these are usually drug companies.

3) Assignees: These are defined by the Act as non-profit patent management organizations, which at the time brokered the license agreements between the contractor and the licensee. Their role has been marginalized in recent years as universities and research institutes have taken on the role themselves.

When reading the march-in clauses, it is important to understand that Section 203a *only* applies to contractors—that is, the original researchers – and assignees.

Section 203a does *not* apply to licensees.

This was not an accidental omission. That licensees are consciously excluded from 203a is obvious, because the next three sections -203b--d explicitly apply to all three entities: contractors, assignees and licensees.

Back in 1980, it was clear that most health inventions could only be practically developed under licenses with the drug industry. Bayh-Dole granted the property rights to the contractor, who would then negotiate a license agreement with the licensee. Of course, drug pricing played *no role* in these negotiations. Pricing a drug which has not yet been tested, approved and marketed is, of course, impossible.

As the phrase "reasonable terms" found in 203a applies to *contractors*, and not to *licensees*, it cannot mean "reasonable prices," because contractors, in the view of the drafters, would not normally be setting prices. Further, they are not required to do so under 202c which sets out all the contractors obligations.

The phrase clearly refers to the terms of the agreement between the contractor and the licensee.

Bayh-Dole wants government-sponsored inventions moved to the marketplace. Towards that end, it obligates the contractor to transfer the invention to the licensee without demanding exorbitant, or unreasonable, *royalties.*

The ultimate price of the drug to be developed had nothing at all to do with section 203a or the contractor's obligations under sec. 202c. Pricing was —and is—left to the discretion of the licensee. It is the licensee, after all, who bears all the risks of developing the innovations—the clinical trials, the FDA approval procedures, the vagaries of the marketplace. They do so because they know that Bayh-Dole guarantees them exclusive rights over the invention.

After explaining all that, I must now point out that Norvir has *never* been licensed, and that Abbott Laboratories is *not* a licensee. It is, in fact, a contractor who obtained title to its invention directly through a contract with NIH.

Again, when the law was written, we thought that in most cases, a contractor would be an academic, research institute or small business that would not have the resources to develop and market the invention on their own. Bayh-Dole therefore emphasizes the licensing process, as is abundantly evident throughout the Act and its implementing regulations.

Abbott Laboratories, as it happens, had no need to license its invention. It had title to the invention and the resources to bring it to the market without any assistance.

This exposes a minor ambiguity in Bayh-Dole. Obviously, "reasonable terms" in this particular case cannot mean "reasonable royalties." But neither can it mean "reasonable pricing", as a requirement under sec.202c.

In other words, we cannot spontaneously reinterpret 203a to mean that when a contractor brings a drug to market itself, it must price the drug

"reasonably". "Reasonable terms" could not mean one thing for a licensee, and another for a contractor, unless the law contained specific language defining these meanings.

The intent of 203a is obvious enough, even if it fails to specifically address the case at hand.

In closing, I'd like to return briefly to the broader issues that have prompted Mr. Love's petition.

It must be plainly understood that medical access problems in the United States stem *not* from the research and development regime, but from the way healthcare entitlements are ascribed and healthcare resources are distributed. Healthcare reform is long overdue. It will be a long, bruising political battle, but the country must, and will, address it.

I confess that I am no fan of price controls, because I believe that they could stifle innovation and drastically reduce the amount of money the drug industry pumps into pharmaceutical research every year. Contrary to what has been published in recent weeks, only a very small portion of the government health research and development funds are channeled directly into drug research and clinical studies. Most is used to sponsor investigations into the life sciences.

It is in fact the private sector that ponies up the resources to develop, test, obtain approval for, and market new drugs. It is an undeniably responsibility of government to create and maintain incentives for these investments, because there is no way the government could manage the job on its own.

In the absence of government price controls, drug companies will seek to maximize their profits by balancing prices with the need for market penetration - and that is exactly what the drafters of Bayh-Dole expected. Pricing freedom is one reason often cited by the pharmaceutical industry for concentrating their research and development activities in the U.S. It is

why the U.S. remains the world leader in medical research, and why so many drugs are made available here first.

That said, the public has an interest in affordable healthcare. I think there are many ways that might be achieved without resorting to outright price controls. State governments, for example, are themselves major purchasers of drugs, and could, through clever use of their market power, help keep prices down.

If a political consensus were to emerge that drug prices need to be controlled by the government, the only legal and appropriate means of instituting such controls would be through a full-fledged legislative process, tested by the courts and administered through empowered organs of government.

Obviously any healthcare reform effort could face resistance from vested interests, and it is tempting for some to look for shortcuts. But twisting intellectual property law into an administrative mechanism to control drug prices would have intolerable consequences for innovation, drug development and healthcare in this country.

It is also legally impossible. A sober reading of the Bayh-Dole Act will leave no doubt that retail drug pricing has nothing to do with the march-in provisions of the Act.

Mr. Love's petition must therefore be denied.

Thank you again for the opportunity to be here today.

WMSH. Post 6/15/04

Robert E. Wittes

Cancer Weapons, Out of Reach

The cancer research community and the patients it serves took heart a few weeks ago from the Food and Drug Administration's approval of two new drugs—Avastin and Erbitux. These are antibodies, similar in structure to the infection-fighting proteins that circulate in our blood. Neither is very effective when used alone, but in combination with other chemotherapy drugs, they can shrink tumors, restrain tumor growth and, in the case of Avastin, extend life by a few months in some patients with colon cancer that has already spread to other parts of the body.

There is just one big problem: Both drugs have been marketed at such extraordinarily high prices that many people will simply not be able to afford them.

Although the new drugs help only a minority of patients, they represent significant successes in translating new molecular knowledge about cancer into more effective treatment. In this respect they join other recent entries in the oncologist's medicine cabinet and are a sign of things to come. Most of us anticipate that truly successful treatment for disseminated cancers will be not with single drugs but with combinations of them, aided by precise molecular testing to guide selection of the most effective drugs for a particular patient.

Now back to the economics. The average wholesale price (AWP, or the average price charged to hospitals and physician practices) of a month of treatment for a normal-size adult is roughly $4,800 for Avastin and $12,000 for Erbitux. Since most colorectal-cancer patients for whom these drugs are medically appropriate receive them not singly but in combination with other chemotherapeutics, the monthly AWP is more like $11,000 for combinations including Avastin and $16,000 for Erbitux. Providers pass these costs on to patients, along with charges that cover the costs of pharmacy and dispensing. Courses of treatment generally last several months, but they can be much longer for patients who respond favorably. In other words, the cumulative cost of treatment can be astronomical.

Access to affordable prescription drugs has been the focus of acrimonious national debate, controversial legislation and regulatory muscle-flexing by the FDA, which opposes, for safety reasons, the importation of prescription drugs from cheaper foreign markets. These new cancer drugs will add fuel to the fire. Although the uninsured and medically indigent may feel the effects of these pricing decisions most keenly, those with insurance will also face a nasty dilemma. The increasing co-pay percentages of most plans and the capping of benefits in others will compel a major financial outlay for those determined to have the treatments. And those who do not want their families to assume the financial burden will be left with bitter resentment.

Third-party payers will not react passively to pricing that increasingly threatens their balance sheets, especially as more drugs like these are commercialized over the next few years. They will carefully scrutinize all proposed uses of expensive new drugs. Historically, an FDA judgment of "safe and effective"—the statutory criterion for drug approval—has almost automatically triggered an agreement by payers to reimburse, which is the real gateway to widespread use and market success. We may now see payers deciding, for the first time, that certain novel "safe and effective" medicines are simply not worth paying for. In addition, payers will surely try to limit "off-label" uses of these drugs—that is, uses other than the FDA-approved ones. Unlike other areas of medicine, physicians have commonly prescribed cancer drugs for a broader array of indications than specifically approved by the FDA, as clinical research routinely reveals additional uses after market introduction. A very high bar to new uses by payers is a virtual certainty.

As desperate cancer patients and their advocacy groups feel critical options narrowing, they will make their sentiments known. When they do, the same members of Congress who incomprehensibly prohibited Medicare from negotiating prices with drug companies will be predictably shocked to find that new drugs cost so much. Congressional committees will hold hearings. Tearful cancer patients and surviving family members will tell their stories to an attentive national audience. Lawmakers will also learn this lesson closer to home, where they will find their own sisters and cousins and aunts in the same boat as everyone else.

The pharmaceutical industry will intone its familiar mantra: The cost of drugs is a relatively small percentage of total health care costs; innovation requires investment; research-based companies need to realize an adequate return on investment; and companies often establish access programs for destitute patients. But these arguments are invalidated by the sheer magnitude of the pricing decisions, which constitute a formidable barrier to the flow of innovation from the research arena to public benefit.

Perhaps their legendary political clout in Washington has convinced drug companies that they can price their goods at arbitrarily high levels. In reaching the stratosphere, however, they are effectively daring the government to impose price controls. This the government must do if the drug industry fails to come to its senses quickly.

The writer is physician in chief at the Memorial Sloan-Kettering Cancer Center in New York.

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MESSAGE:

NATIONAL INSTITUTES OF HEALTH
OFFICE OF THE DIRECTOR

In the Case of

NORVIR®

Manufactured by

ABBOTT LABORATORIES, INC.

Introduction

The NIH received letters from members of Congress and the public requesting that the Government exercise its march-in rights under the Bayh Dole Act (Act), 35 U.S.C. §§ 200-212, in connection with one or more patents owned by Abbott Laboratories, Inc. (Abbott). The letters expressed concern over the price of Norvir®, which is covered by the patents and marketed by Abbott for the treatment of patients with HIV/AIDS.

The march-in provision of the Act, 35 U.S.C. § 203, implemented by 37 C.F.R. § 401.6, authorizes the Government, in certain specified circumstances, to require the funding recipient or its exclusive licensee to license a Federally-funded invention to a responsible applicant or applicants on reasonable terms, or to grant such a license itself.

After careful analysis of the Bayh-Dole Act and considering all the facts in this case as well as comments received, the National Institutes of Health (NIH) has determined that it will not initiate a march-in proceeding as it does not believe that such a proceeding is warranted based on the available information and the statutory and regulatory framework.

Background on the Invention

From 1988 through 1993, ritonavir was developed at Abbott Laboratories partly through the use of Federal funds and falls within the claims of a number of patents owned by Abbott.[1] In 1996, ritonavir (sold under the tradename "Norvir®") was approved by the FDA for marketing.

Other U.S. and foreign patents may exist which cover certain aspects of the marketed compound including specific formulations or delivery techniques, and may not be subject inventions within the meaning of the term as defined in 35 U.S.C. § 201(e).[2] These inventions would not be

[1]These patents are: U.S. Patent Nos. 5,541,206, 5,635,523, 5,648,497, 5,674,882, 5,846,987, and 5,886,036.

[2]The term "subject invention" means any invention of the funding recipient conceived or first actually reduced to practice in the performance of work under a funding agreement.

subject to the Government's march-in authority.

Statutory and Regulatory Background

The stated policy and objective of the Bayh-Dole Act is:

> to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; 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; and to minimize the costs of administering policies in this area.

Act at § 200. Toward this goal, the Act addresses not only rules governing the licensing of Government-owned inventions, but also addresses the rights of Federal contractors[3] to elect title to inventions made with Federal funding.

In giving contractors the right to elect title to inventions made with Federal funding, the Act also includes various safeguards on the public investment in the research. For example, the Federal agency retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. See 35 U.S.C. § 202(c)(4). In addition, the Act includes march-in rights which provide a Federal agency with the authority, in certain very limited and specified circumstances, to make sure that a federally funded invention is made available to the public. The march-in provisions are set out in Section 203(a), which states that:

> With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a

[3] Section 201(c) defines the term "contractor" as any person, small business firm, or nonprofit organization that is a party to a funding agreement. Executive Order 12591 expanded this definition to include large businesses.

nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such -

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The Department of Commerce regulations implementing the Act and specifying the procedures that govern the exercise of march in proceedings are set forth at 37 C.F.R. § 401.6. The regulations provide that whenever an agency receives information that it believes miglit warrant the exercise of march-in rights, it may initiate a march-in proceeding after notification of the contractor and a request to the contractor for informal written or oral comments.

Public Comments

The NIH held a public meeting on May 25, 2004 at which comments were presented by advocates foT and against the use of the Government's march-in authority in connection with Norvir®. The speakers presented differing perspectives regarding the interpretation and intention of the march-in provisions, the reasons for the increase in the price of ritonavir, and the anti-competitive effect of that price increase.

The NIH also has received written comments from a variety of groups and individuals representing universities, the AIDS community, pharmaceutical interests, drafters of the Bayh-Dole Act, and other interested parties. These comments along with those submitted at the public meeting are available on the NIH Office of Technology Transfer website at http://ott.od.nih.eov/Meeting/Mav25.htm.

The NIH is aware that members of Congress and the public have asked the Federal Trade Commission (FTC) to investigate the potential anti-competitive effects of the increase in the

price of Norvir®. The NIH agrees that the FTC is the appropriate agency to address this issue.

After carefully considering all the information provided and otherwise made available, the NIH does not believe the initiation of a march-in proceeding is warranted.

Discussion

The NIH is the steward of medical and behavioral research for the nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Each year, a wealth of scientific discoveries emanates from the NIH intramural laboratories and from extramural activities under grants and contracts. Bringing these discoveries from "the bench to the bedside" requires drug and product development, scale-up, clinical testing, and finally marketing and distribution. Success in accomplishing this colossal task and fulfilling our primary mission of improving public health requires the participation of industry partners.

The NIH supports fundamental research that may lead to the development of pharmaceutical products. Occasionally, the NIH funds a technology that ultimately is incorporated into a commercial product or process for making a commercial product. It is important to the NIH that pharmaceutical companies commercialize new health care products and processes incorporating NIH-funded technology thereby making the technology available to the public. A central purpose of the Bayh-Dole Act involves the development and commercialization of such products out of federally-funded research.

Section 203(a) of the Act provides in part that march-in rights maybe exercised by the funding Federal agency based on any of four conditions: (1) when "practical application" of the subject invention has not been achieved or is not expected to be achieved in a reasonable time, (2) when the action is necessaiy to alleviate health or safety needs, (3) when action is necessary to meet requirements for public use specified by Federal regulation that the contractor has failed to meet or (4) when the U.S. industry preference of Section 204 of the Act has not been met. The third and fourth conditions are not relevant to this discussion[4]..

Practical Application of the Subject Inventions

A composition or product, such as Norvir®, that has achieved practical application is defined in Section 201 (f) to mean that it is manufactured "under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."

[4] The last two conditions are clearly not relevant. Subparagraph (3) narrowly applies to "public use" specified by Federal regulations, but there are no regulations that apply in this case. Subparagraph (4) is not relevant because Abbott manufactures Norvir® in the United States.

In 1997, the NIH reviewed a march-in request from CellPro, Inc. that asserted Baxter Healthcare Corporation (Baxter) had failed to take effective steps to achieve practical application of the subject inventions. NIH determined that Baxter "met the statutory and regulatory standard for practical application" as evidenced by its "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public____" Accordingly, the NIH determined not to initiate march-in proceedings.[5]

Similarly, the record in this instance demonstrates that Abbott has met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of ritonavir and the drug's availability and use by the public.

Ritonavir has been on the market and available to patients with HIV/AIDS since 1996, when it was introduced and sold under the tradename Norvir® as both a standalone protease inhibitor and a booster to increase the effectiveness of protease inhibitors marketed by other companies. Thus, the invention has reached practical application because it is being utilized and has been made widely available for use by patients with HIV/AIDS for at least eight years.

Health or Safety Needs

Norvir® has been approved by the Food and Drug Administration as safe and effective and is being widely prescribed by physicians for its approved indications. No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by Abbott. Rather, the argument advanced is that the product should be available at a lower price, which is addressed below. Thus, the NIH concludes that Abbott has met the statutory and regulatory standard for health or safety needs.

Drug Pricing

Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand.[6] In addition, because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling

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[5]The determination also evaluated the health or safety need prong and found that Baxter had "taken appropriate steps to reasonably satisfy this need." The other two prongs were held to be "clearly not relevant."

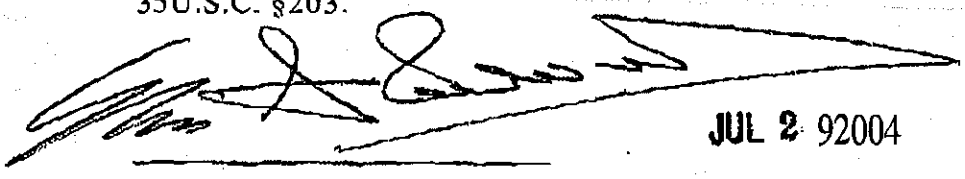
[6]In addition, NIH addressed "The NIH 'Reasonable Pricing* Clause Experience" in its report to Congress, "A Plan to Ensure Taxpayers' Interests are Protected," July 2001, available at http://www.nih.gov/news/070101wyden.htm.

prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.

Conclusion

Norvir® has been available for use by patients with HIV/AIDS since 1996 and is being actively marketed by Abbott and prescribed by physicians primarily as a booster drug. Accordingly, this drug has reached practical application and met health or safety needs as required by the Bayh-Dole Act. The NIH believes that the issue of drug pricing is one that would be more appropriately addressed by Congress, as it considers these matters in a larger context. The NIH also maintains that the FTC is the appropriate agency to address the question of whether Abbott has engaged in anti-competitive behavior.

The NIH is cognizant of the care with which Congress crafted the march-in language and understands that it has the responsibility to exercise its march-in authority deliberately and with great care. As such, the NIH has determined that it does not have information that leads it to believe that the exercise of march-in rights might be warranted in this case within the meaning of 35U.S.C. §203.



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Elias A. Zerhouni, M.D.
Director, NIH

Scholars, Hucksters, Copycats and Frauds

By STEPHEN GILLERS

When athletes or entertainers appear in an advertisement to pitch a product—Bob Dylan for Victoria's Secret, say, or Tiger Woods for American Express—no one takes the endorsement at face value. We know they are doing it for the money, so we're on guard. But we let down our guard for some groups—among them the clergy, judges and scholars. We may not always agree with what they say, but we assume candor and a certain independence.

Scholars enjoy our trust because of a seemingly airtight line of reasoning: Educators are in the knowledge business, the cornerstone of knowledge is truth, the pursuit of truth demands integrity and integrity requires candor. So when educators talk, we assume that we're not being conned. But exploitation of this trust is apparently irresistible to public relations firms whose clients want to influence public opinion. We should not be surprised, therefore, to learn that PR firms look for well-credentialed scholars willing to put their names on op-ed pieces written by the firms and advocating their clients' views. An op-ed from an established scholar, after all, is a whole lot more persuasive than a paid advertisement.

Scholars who lend their names and titles to ghostwritten op-eds that are meant to advance the commercial or political interests of others betray the public trust. Their conduct deceives the newspaper that publishes the op-ed and its readers—but worse, it threatens our faith in the educational enterprise. This is the academic equivalent of turning back a used car's odometer, but the potential harm is greater. We know to be careful when buying a used car. We are encouraged to trust scholars, but won't for long if they become shills for private interests.

Plagiarism has several meanings. The theft of an unsuspecting author's work is one example, perhaps the most common. Plagiarism can also occur without theft. In the case of professors passing off op-eds as their own, the author (who prefers to remain hidden) not only knows about the use of his or her words, but *wants* the educator to use the work.

A student who buys a term paper and submits it as his own has plagiarized. That's not exactly what's going on in the examples described by William M. Adler in today's Outlook, but it's close. Instead of a grade and course credit, the educator gets published in a newspaper and an ego boost.

Asking whether this practice constitutes plagiarism may not be the best way to analyze the matter. Instead, we should see it as a form of intellectual fraud. When someone lies about an important fact to sell you a product, he's perpetrating a fraud. Here, the lie is fake authorship and the product is an idea. Intellectual fraud is not a crime. But it is wrong.

To see clearly why it is wrong—why it is intellectual fraud—imagine that an enlisted scholar, in a moment of candor, submits his ghostwritten op-ed with a disclaimer that reads: "This article was written by an industry's public relations firm but I agree with it." What would happen? It would not be published. If by some unimaginable editorial lapse it was published anyway, readers would ignore it or write irate letters to the paper. The true author and the fake author know that, of course, which is why the disclaimer does not appear. They conceal the truth so the newspaper will print the op-ed and readers will be encouraged to accept the ideas as valid. A deception to sell a product.

Let's make some important distinctions. First, this is quite different from the practice of professors hiring students to do research and write first drafts. Using student researchers is a way to train the next generation of scholars. Further, professors are expected to design the research methodology and objectives, and to closely monitor the students' work. They are also expected to give students credit in whatever they publish. Nothing is hidden. Nor are we talking about ghostwriters who prepare articles, speeches or books for those who may be too busy to do it themselves. When a governor or a CEO gives a speech or a celebrity publishes an autobiography, we will not feel deceived if we learn that someone else wrote the words. Writing books and speeches is not the essence of their work. We expect only that the ideas are ones the governor or CEO truly holds and that the celebrity's life is accurately portrayed.

Scholars are different. Formulating and expressing ideas is precisely their job. In exchange for pledging themselves to the discovery of knowledge, a pursuit that benefits all, scholars are richly rewarded. Not in money perhaps, but in prestige, in free time to think and write and, through tenure, in immunity from market vicissitudes. These benefits come at a price, however.

Scholars may not subcontract the heavy lifting of factual investigation and intellectual analysis to others, providing only the wrapper—name and title—for the final product. "What's the difference who wrote it," the fake author might protest, "so long as I agree with it? Isn't that enough?"

Not in my book. Scholarship is not just a bottom line—an idea or a discovery. It is also the rigorous methodology that led to the idea or discovery. Anyone who has ever written an essay defending an opinion knows that the very act of writing educates the writer, and influences the shape and form of the opinion. When in articles or books, therefore, a scholar tells us that something is true or right, we are entitled to believe that he participated in the process that led him to that conclusion and in the manner in which it is expressed. If the author is relying on the work of others, he is required to cite it.

No law can stop intellectual fraud. The First Amendment will even protect this shoddy practice. But it can be stopped by the institutions whose credentials make the abuse possible in the first place—colleges and universities—and by the emphatic disapproval of academic colleagues. And they have incentive to do so. Aside from the public harm, this corrosive practice threatens them most of all.

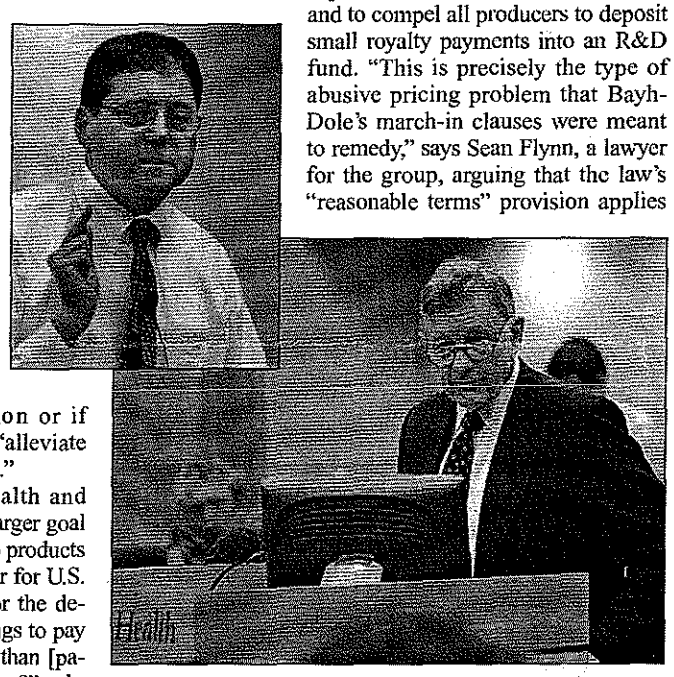
Stephen Gillers teaches legal ethics at New York University School of Law, where he is vice dean and a professor of law.

INTELLECTUAL PROPERTY

NIH Weighs Demand to Force Sharing of AIDS Drug Patents

The government's interpretation of a 25-year-old law giving federally funded researchers the right to patent and commercialize their discoveries was put to the test last week. AIDS activists want the National Institutes of Health (NIH) to use its legal muscle to rein in the spiraling domestic cost of an important AIDS drug. But major research universities and former government officials who wrote the law say that if the activists got their way, it would damage efforts to commercialize academic discoveries.

At the heart of the conflict are two provisions of the 1980 Bayh-Dole Act. One says that government-funded inventions should be "available to the public on reasonable terms." The other gives funding agencies the right to "march in" and force a patent holder to license its inventions to other companies if the existing license holder isn't taking "reasonable" steps to develop the invention or if change is needed to "alleviate health or safety needs."



Bye-bye Bayh-Dole? Former Senator Birch Bayh (*above*) says NIH would undermine innovation policy if it intervened on Abbott patents, as James Love's Essential Inventions group has requested.

But balancing health and safety needs with the larger goal of turning research into products can get tricky. "Is it fair for U.S. taxpayers who paid for the development of these drugs to pay five to 10 times more than [patients] in other countries?" asks James Love of Essential Inventions, a Washington, D.C.–based advocacy group. He says NIH should act to "protect the notion that [the law] is a fair bargain [and not] an unmitigated giveaway." Opponents agree—to a point. "While I'm sympathetic to the effort, ... twisting intellectual-property law to control drug prices would be intolerable," said Norman Latker, a retired NIH general counsel.

The battle was joined in January when Essential Inventions asked NIH to march in on four patents held by Abbott Laboratories of Chicago, Illinois. It claimed that the firm was profiteering on a widely used AIDS drug called Norvir (www.essentialinventions.org). A 25 May hearing at NIH heard comments on the petition.

Norvir is used to boost the effectiveness of other anti-HIV medications. It was developed in the early 1990s by Abbott researchers supported by a 5-year, $3.5 million NIH grant awarded in 1988, and the government has a stake in four of the six patents covering the drug. Norvir has been on the market since 1996, but last year Abbott increased U.S. retail prices for some formulations by up to 400%.

Health care activists want the government to force Abbott to roll back prices. The Essential Inventions petition, for instance, asks NIH to require the company to license the four patents to competing manufacturers and to compel all producers to deposit small royalty payments into an R&D fund. "This is precisely the type of abusive pricing problem that Bayh-Dole's march-in clauses were meant to remedy," says Sean Flynn, a lawyer for the group, arguing that the law's "reasonable terms" provision applies to drug pricing.

That view, however, was disputed by a string of witnesses—including the law's co-author. "We never intended for [Bayh-Dole] to be used to control prices. We stayed away from that on purpose," said former Indiana senator Birch Bayh (D), who sponsored the legislation with former Kansas senator Bob Dole (R). Essential Inventions "flagrantly misrepresent[ed]" the law's legislative history and intent in its petition, he added.

Two university groups—the Association of American Universities (AAU) and the Council on Governmental Relations (COGR)—agree with Bayh and predicted that companies would refuse to invest in ▶

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ScienceScope

Japan May Up Ante for ITER

TOKYO—Japan may significantly increase its contribution to the International Thermonuclear Experimental Reactor (ITER) in a bid to land the stalled project, according to news reports in Japan. Officials are discussing boosting the nation's contribution from about 48% to as much as 65% of the total $10 billion construction and operating cost, the reports suggest. Government officials, however, declined to confirm the reports for *Science*.

The partners can't agree on where to build the reactor. The European Union, Russia, and China favor a site in Cadarache, France, whereas the United States, South Korea, and Japan back Rokkasho, Japan. Another meeting is planned later this month.

–DENNIS NORMILE

Pacific Salmon Status Mostly Unchanged

A controversial decision by federal officials to count hatchery fish in deciding whether Pacific salmon populations are endangered has not led to the widespread delisting that some observers feared (*Science*, 7 May, p. 807). The National Oceanic and Atmospheric Administration announced last week that 26 salmon populations being reviewed will remain on the protected list; just two will be downgraded from "endangered" to "threatened."

Salmon advocates are relieved, but property owner groups that won the 2001 court decision forcing the agency to consider counting hatchery fish vowed to take the new decision back to court.

–JOCELYN KAISER

U.S. Laureate to Head South Korean Science Institute

SEOUL—A U.S. Nobel laureate has been picked to become president of the Korea Advanced Institute of Science and Technology (KAIST), the first time that a foreigner has headed any Korean university.

Robert Laughlin, who won the 1998 physics prize for discovering a new form of quantum fluid, is a professor at Stanford University in Palo Alto, California, with extensive ties to Korea. His appointment still must be approved by the Ministry of Science and Technology. "This is not a done deal yet," says Laughlin, who last month was named director of the Asia Pacific Center for Theoretical Physics in southeastern Korea. The KAIST post, a 4-year appointment, is full-time. But Laughlin says he remains "strongly committed" to his current work.

–MARK RUSSELL

taxpayer-funded inventions if NIH granted the petition. "It's a misapplication of the statute ... [that] would likely have serious unintended and adverse consequences," said AAU representative Theodore Poehler, vice provost for research at Johns Hopkins University in Baltimore, Maryland. "It would be a major deterrent to licensing inventions ... if potential licensees believe the government has authority" to control prices, added COGR representative Andrew Neighbour, a law professor at the University of California, Los Angeles.

NIH officials gave little hint after the hearing of how they will rule. Mark Rohrbaugh, head of the agency's technology-transfer office, said he plans to "move expeditiously" to make a recommendation to NIH Director Elias Zerhouni, who will make the final decision. Although many legal observers predict that NIH will reject the petition, Love is hoping for a boost from election-year politics. "Drug pricing is a big political issue" that President George W. Bush won't want to hand to his opponent, he says. Love has also asked NIH to exercise march-in rights on another drug, Pfizer's Xalatan glaucoma treatment, which he says costs up to five times more in the United States than abroad. –DAVID MALAKOFF

DEVELOPMENT SPENDING

Economists Rate Greenhouse Gas Curbs a Poor Investment

COPENHAGEN—Feel like throwing your tax money away? Invest in measures to rein in global warming. That's the controversial conclusion, at least, of a workshop here last week that brought together a varied group of economists, including three Nobel laureates, to analyze spending on global problems.

Participants of the "Copenhagen Consensus" weren't purely naysayers: They lauded, as money well spent, initiatives proposed to combat AIDS, malaria, and malnutrition, for example. "This will help us focus on the more important problems," says workshop organizer Bjørn Lomborg, director of the Environmental Assessment Institute in Copenhagen.

Many scientists don't buy that argument, however. "We shouldn't be spending less on climate change so we can spend more on sanitation. The problems are interrelated," says Stephen Schneider, a climatologist at Stanford University, who labels the workshop's premise "phony and a distortion."

The stated premise was that the industrialized world has limited funds—about $50 billion a year—for aid to developing countries and no objective way to set priorities. According to Lomborg, author of *The Skeptical Environmentalist*—a 2001 book that sought to discredit a host of environmental concerns (*Science*, 2 January, p. 28)—"eco-myths" such as global warming "prevent us from acting rationally" when committing resources to improving the world. It would be better, he argues, to base spending on cost-benefit ratios. Measures to stem climate change should compete for development aid, Lomborg suggests, because according to predictions "the developing world will suffer most of the damage from climate change."

With backing from the prime minister of the right-leaning Danish government, Lomborg invited the nine economists who attended—including Nobelists Robert Fogel of the University of Chicago, Douglas North of Washington University in St. Louis, Misouri, and Vernon Smith of George Mason University in Fairfax, Virginia—to rank solutions to pressing problems according to their likely return on investment. Experts, chosen by Lomborg, argued for and against each of 10 "challenges" (see table).

Laying out the case for climate change was William Cline, an environmental economist at the Center for Global Development in Washington, D.C. His primary evidence was the 2001 report of the Intergovernmental Panel on Climate Change (IPCC), which predicts an increase in average global temperatures of between 1.4° and 5.8°C by the year 2100. Lomborg acknowledged that the report is "the best of our knowledge on climate change." The economic benefits of stemming global warming include protecting the lives of income-generating human beings as well as arable land. Steps to limit warming center on reducing emissions of greenhouse gases such as carbon dioxide, a tenet of the Kyoto Protocol. The most cost-effective strategy, Cline argued, would be a global carbon tax, more aggressive than the one called for under Kyoto, that would halve greenhouse emissions by the end of the century.

The 10 Challenges

- Armed conflicts
- Climate change
- Communicable diseases
- Education
- Financial instability
- Governance and corruption
- Malnutrition and hunger
- Population and migration
- Sanitation and water
- Subsidies and trade barriers

The panel rejected that line of argument, concluding that Cline's proposals would be "very bad" investments. Panelist Nancy Stokey, an economist at the University of Chicago, explains that the solutions would require "large expenditures for benefits that would come far in the future." Even with a less limited budget, the Kyoto Protocol, in the panel's view, is not worthwhile.

That leaves scientists such as Schneider, a lead author of the IPCC report, fuming. "Climate change is not an economics problem. It's an ethics problem," he says. Adds John Holdren, an environmental policy expert at Harvard University, "One can't help suspecting ... that Lomborg has stacked both the participants list and the framing of the questions to achieve this result."

Lomborg rejects that charge, arguing that the workshop's organization was "unbiased." He acknowledges, though, that the panel was short on environmental expertise. "I invited other economists," who declined to come, he says, dismissing his critics as "conspiracy theorists." Lomborg plans to distribute the panel's conclusions to governments and to the United Nations.

Illustrating how influential Lomborg is perceived to have become, environmental economists convened an alternative conference, "Global Conscience," in Copenhagen last week to discuss sustainable development. "We shouldn't choose between poverty eradication and prevention of climate change," says co-organizer Christian Jørgensen, chair of the nonprofit Danish Ecological Council. "Prevention of climate change will pay off; it will reduce our dependence on Middle East oil, and it will create a new industrial sector for renewable energy and energy conservation." Clearly, economics alone won't reconcile these sharply divergent world views.

–JOHN BOHANNON

John Bohannon is a writer based in Berlin.

Stacked deck? Bjørn Lomborg (right) with Danish Prime Minister Anders Fogh Rasmussen.

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WMSH. Post 6/15/04

Robert E. Wittes

Cancer Weapons, Out of Reach

The cancer research community and the patients it serves took heart a few weeks ago from the Food and Drug Administration's approval of two new drugs—Avastin and Erbitux. These are antibodies, similar in structure to the infection-fighting proteins that circulate in our blood. Neither is very effective when used alone, but in combination with other chemotherapy drugs, they can shrink tumors, restrain tumor growth and, in the case of Avastin, extend life by a few months in some patients with colon cancer that has already spread to other parts of the body.

There is just one big problem: Both drugs have been marketed at such extraordinarily high prices that many people will simply not be able to afford them.

Although the new drugs help only a minority of patients, they represent significant successes in translating new molecular knowledge about cancer into more effective treatment. In this respect they join other recent entries in the oncologist's medicine cabinet and are a sign of things to come. Most of us anticipate that truly successful treatment for disseminated cancers will be not with single drugs but with combinations of them, aided by precise molecular testing to guide selection of the most effective drugs for a particular patient.

Now back to the economics. The average wholesale price (AWP, or the average price charged to hospitals and physician practices) of a month of treatment for a normal-size adult is roughly $4,800 for Avastin and $12,000 for Erbitux. Since most colorectal-cancer patients for whom these drugs are medically appropriate receive them not singly but in combination with other chemotherapeutics, the monthly AWP is more like $11,000 for combinations including Avastin and $16,000 for Erbitux. Providers pass these costs on to patients, along with charges that cover the costs of pharmacy and dispensing. Courses of treatment generally last several months, but they can be much longer for patients who respond favorably. In other words, the cumulative cost of treatment can be astronomical.

Access to affordable prescription drugs has been the focus of acrimonious national debate, controversial legislation and regulatory muscle-flexing by the FDA, which opposes, for safety reasons, the importation of prescription drugs from cheaper foreign markets. These new cancer drugs will add fuel to the fire. Although the uninsured and medically indigent may feel the effects of these pricing decisions most keenly, those with insurance will also face a nasty dilemma. The increasing co-pay percentages of most plans and the capping of benefits in others will compel a major financial outlay for those determined to have the treatments. And those who do not want their families to assume the financial burden will be left with bitter resentment.

Third-party payers will not react passively to pricing that increasingly threatens their balance sheets, especially as more drugs like these are commercialized over the next few years. They will carefully scrutinize all proposed uses of expensive new drugs. Historically, an FDA judgment of "safe and effective"—the statutory criterion for drug approval—has almost automatically triggered an agreement by payers to reimburse, which is the real gateway to widespread use and market success. We may now see payers deciding, for the first time, that certain novel "safe and effective" medicines are simply not worth paying for. In addition, payers will surely try to limit "off-label" uses of these drugs—that is, uses other than the FDA-approved ones. Unlike other areas of medicine, physicians have commonly prescribed cancer drugs for a broader array of indications than specifically approved by the FDA, as clinical research routinely reveals additional uses after market introduction. A very high bar to new uses by payers is a virtual certainty.

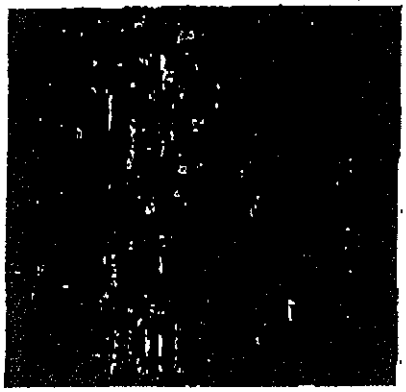
As desperate cancer patients and their advocacy groups feel critical options narrowing, they will make their sentiments known. When they do, the same members of Congress who incomprehensibly prohibited Medicare from negotiating prices with drug companies will be predictably shocked to find that new drugs cost so much. Congressional committees will hold hearings. Tearful cancer patients and surviving family members will tell their stories to an attentive national audience. Lawmakers will also learn this lesson closer to home, where they will find their own sisters and cousins and aunts in the same boat as everyone else.

The pharmaceutical industry will intone its familiar mantra: The cost of drugs is a relatively small percentage of total health care costs; innovation requires investment; research-based companies need to realize an adequate return on investment; and companies often establish access programs for destitute patients. But these arguments are invalidated by the sheer magnitude of the pricing decisions, which constitute a formidable barrier to the flow of innovation from the research arena to public benefit.

Perhaps their legendary political clout in Washington has convinced drug companies that they can price their goods at arbitrarily high levels. In reaching the stratosphere, however, they are effectively daring the government to impose price controls. This the government must do if the drug industry fails to come to its senses quickly.

The writer is physician in chief at the Memorial Sloan-Kettering Cancer Center in New York.

Innovation's golden goose



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Comments on any of these topics are welcome at www.economist.com/forums/tq

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

REMEMBER the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

The result was that inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

The Bayh-Dole act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. Odd, then, that the Bayh-Dole act should now be under such attack in America.

No free lunch

There has always been a fringe that felt it was immoral for the government to privatise the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?

That is easily answered. Invention, as TQ has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost.

Then there is the American Bar Association, which has lobbied hard to get the government's "march-in" rights repealed. The government has kept (though rarely used) the right to withdraw a licence if a company fails to commercialise an invention within a reasonable period. This was to prevent companies from licensing academic know-how merely to block rival firms from doing so. The lawyers argue that the government could use its walk-in rights to bully pharmaceutical firms into lowering the price of certain drugs.

Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot. Readers who agree or disagree can share their own views at www.economist.com/forums/tq.

BROWDY AND NEIMARK, P.L.L.C.
ATTORNEYS AT LAW
PATENT AND TRADEMARK CAUSES
SUITE 300
624 NINTH STREET, N.W.
WASHINGTON, D. C. 20001-5303
TELEPHONE (202)-628-5197

SHERIDAN NEIMARK
ROGER L. BROWDY

ANNE M. KORNBAU
NORMAN J. LATKER
DIANA MICHELLE SOBO
AOI NAWASHIRO
HEIDI M. STRUSE, PH.D.

OF COUNSEL
IVER P. COOPER
JAY M. FINKELSTEIN

ALVIN BROWDY (1917-1998)

PATENT AGENT
ALLEN C. YUN, PH.D.

TELECOPIER FACSIMILE
(202) 737-3528
(202) 393-1012

E-MAIL
mail@browdyneimark.com

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Yes, America Has a 'New Economy': Technology

Federal Reserve Chairman Alan Greenspan gave unexpected support to "New Economy" theorists in a speech at the Gerald R. Ford Foundation in Grand Rapids 13 days ago. Information technology, he said, "has begun to alter, fundamentally, the manner in which we do business and create economic value." By enabling businesses to remove "large swaths of unnecessary inventory," real-time information is accelerating productivity growth and raising living standards. This has contributed to the "greatest prosperity the world has ever witnessed."

Global View

By George Melloan

That is bullish talk for a man better known for chiding Wall Street for its "irrational exuberance," long before the Dow soared above 11,000. There can be little doubt, however, that there is a new, technology-based economy roaring toward the year 2000 and that Americans are its primary driving force. So it is fascinating to contemplate what new technological marvels we're likely to see in the 21st century. Just as engaging is reflection on why it is that the U.S. has become the fountainhead of creativity in science and engineering. A lot of other nations would like to find the secret and bottle it.

But first a look at some of the hot technologies, some gleaned from a bibliography prepared by the Organization for Economic Cooperation and Development in Paris. OECD researchers expect further dramatic advances in information technology, with desktop computers heading onward and upward in memory and speed. Gene-replacement therapy could be widespread by 2025, as the Human Genome Project unlocks further mysteries of the human body.

Meanwhile, Rand Corp's Critical Technologies Institute, surveying corporate executives, forecasts that over the next 20 years "molecular medicine" will lead to powerful medications and therapies that treat diseases at the genetic level. Therapy will be applied at earlier stages of disease and will be adapted to individual patients. These more precise treatments will further advance life expectancies.

"The same deeper understanding of genetics that is poised to revolutionize health care and its attendant industries also offers the potential for more precisely breeding plants and animals," says the Rand survey. "Depending on consumer acceptance, by the early part of the next century, much of the world's produce may be genetically engineered in some way."

Materials technology is a wide-open field, with possibilities for flexible glass or ceramics and, most fascinating, the marriage of biology and engineering to produce combinations of organic and inorganic materials that are, in effect, self-assembling. Tiny sensors will someday eliminate the need for highway toll booths and regulate automobile engines, in both cases saving enormous amounts of fuel. Imaging technology is progressing toward identifying tinier objects, advancing molecular medicine and genetic engineering.

In transportation, look for the "hybrid car" early in the 21st century, using fuel cells, an advanced electrical battery. "Over the longer term, fuel cells, combined with super-strong, ultra-light polymers or ceramics, could provide true energy savings for the transportation sector," the Rand study says.

The reason the U.S. is leading the technological revolution is partly its great wealth. Its corporations, universities and national laboratories are the world's leading spenders on research and development, with outlays double the nearest rival, Japan. But there is a lot more to this great burst of creativity than just the amount of money spent. Far more important is the environment that Americans have created—or perhaps preserved is a better description—that fosters and rewards creative effort.

The Bayh-Dole Act of 1980 allows recipients of government grants to retain title to their inventions. Says a study on basic research by the Committee for Economic Development: "This law has stimulated intense growth in university patenting and a subsequent technology transfer from basic research institutions to industry. As a result, industry is increasingly involved in collaboration with, and sponsorship of, university-based researchers." For example, the CED report notes that there are 1,000 companies in Massachusetts with relationships with the Massachusetts Institute of Technology. Their worldwide sales are $53 billion. "Similar developments have taken place in California's Silicon Valley and the Research Triangle of North Carolina."

Genetics research will revolutionize health care.

But many places elsewhere in the world are lacking one or more of the magic ingredients that have made the U.S. the great dynamo of the technological revolution. No country, for example, can match America's vast network of colleges and universities, teaching hospitals and private-research institutions, not to mention the labs of its multinational corporations. These centers of research attract aspiring scientists and engineers from all over the world and many find the intellectual climate so much to their liking that they settle permanently in the U.S.

U.S. national laboratories, though suffering from the usual inefficiencies of tax-supported institutions, nonetheless direct grants to thousands of individuals who are pursuing promising lines of research. And the ease with which individuals can start businesses in the U.S., in sharp contrast to Europe and Asia, means that good ideas spawn new firms, which often grow large and provide shelter and stimulation for new generations bent on making their marks in research and development.

But there is more to it than that. The U.S. would never have arrived at this stage without the changes in the public-policy environment that have transpired over the last 20 years. Ronald Reagan set in motion a deregulatory and tax reform process that has survived to this day. Efforts by the Clintons to nationalize the health industry, which surely would have stultified medical research, failed. So did the effort of Vice President Al Gore to whip up "environmental" hysteria and thus expand the regulatory burden, which is a particular curse for small start-up firms, at a faster rate.

Another Rand study comparing the U.S. with the European Union, Japan, China and South Korea shows that the U.S. leads in providing a climate of openness to foreign trade and investment. This helps make the U.S. economy highly competitive. Competition stimulates innovation. That is reflected in Rand statistics showing that American industry sharply expanded its employment of Ph.D. scientists and engineers between the years 1973 and 1991, increasing its share, relative to other employers, to 36% from 24%.

There are lessons in all this. All this new science didn't just happen. It had to be incubated. If the U.S. can preserve the environment that hatches inventions, it can look forward with optimism to the 21st century. Present evidence suggests that the 21st may even outstrip the 20th as a century of science.