
PART 7

Secrecy in Science and Access to Scientific Data

Historically, the debate concerning secrecy in science had centered on striking a balance between government's concern for maintaining national security and the scientific community's desire for the open exchange of ideas and information. Today, the increasing commercial value of academic research has shifted the focus to issues of intellectual property, as witnessed by the proliferation of worldwide patents, and non-disclosure and reach-through agreements. Additionally, a new type of secrecy has arisen in the form of what can and cannot be studied. Questions over the ethics of some research have attracted the interest of policymakers around the world, who have passed restrictions on limited funding of research on genetically modified organism, and human stem cells.

In March 1999, AAAS and the Massachusetts Institute of Technology (MIT) co-sponsored a Colloquium on Secrecy in Science. The Colloquium, which was held on the MIT campus in Cambridge, Massachusetts, gathered experts in the fields of health research, intellectual property, and encryption to examine past and present issues in scientific secrecy. This section includes three papers that are based on remarks delivered at that Colloquium.

In Chapter 25, Senator Daniel Patrick Moynihan (D-NY), outlines the recent history of secrecy in the United States. As a member of the bipartisan Commission on Protecting and Reducing Government Secrecy, Moynihan reviewed the model the federal government uses to issue security clearances and classify and declassify information. He draws on his wealth of experience on the topic to provide a number of anecdotes concerning the uses and misuses of secrecy policy. He begins by stating, "Of the many institutions of American government that emerged in the course of the 20th century, none has received, in relation to its importance, so little attention as that of secrecy." He discusses the development of policy shaping government secrecy in the U.S., from the Secrecy Act of 1917, to the Report of the Commission on Protecting and Reducing Government Secrecy in 1997, and the 1998 Government Secrecy Reform Act. According to Moynihan, secrecy "remains a hidden, enormous, metastasizing mass within government itself." He im-

plies that much of what gets classified as secret “are pure creatures of bureaucracy via Executive Orders.”

Robert Cook-Deegan, director of the National Cancer Policy Board, addresses the cost of secrecy and its effect upon innovation and product development, and the dependence of technological advancement on the free flow of information. He poses the question, “does secrecy become sludge in the scientific pipeline?” Cook-Deegan works from the thesis that openness fosters innovation, and that many of the instruments designed to protect “the initiator’s bottom line,” may be harming society. He states that information flow problems are becoming common in genomics and other fields. These information logjams typically result from a firm “pursuing worldwide patent rights, seeking a royalty stream, signing nondisclosure agreements, and establishing licensing agreements for access to materials or information.” He believes however, that the federal government may be able to provide a means of freeing information flow through federal funding mechanisms, modifications to the Bayh-Dole Act, or a re-tooling of patent law. He concludes by suggesting that the solution rests with the research universities themselves. “If there were one thing I could do to reduce the level of secrecy that can impede innovation, it would be to elevate norms of open communication of knowledge in academe, and clearly subordinate the business interests in intellectual property management to education and research at academic institutions.”

Howard Schachman of the University of California at Berkeley discusses government-imposed and self-imposed “new secrecy” in science in Chapter 27. He defines the term “New Secrecy in Science” as “any type of restriction that impedes or limits the freedom to pursue research and to disseminate the results of investigations...” Government-imposed secrecy thus manifests itself in the form of the prohibition on certain types of research involving human embryos, and fetal tissue. It is further shown through efforts to amend Circular A-100 to use the Freedom of Information Act (FOIA) as a means for gaining access to research data. Although modified in its final form, Schachman believes that using FOIA for this purpose will actually “hinder the open exchange of information and ideas” and “still permit some potential harassment” of scientists. Schachman further explains that self-imposed secrecy refers to institutions as well as scientists. Schachman proposes that blame for the new secrecy lies with the government, and that a partial correction can be achieved by re-appraising the twenty-year-old Bayh-Dole Act that encourages institutions to “patent discoveries made through government-sponsored research.”

25 The Science of Secrecy

Senator Daniel Patrick Moynihan

Of the many institutions of American government that emerged in the course of the 20th century, none has received, in relation to its importance, so little attention as that of secrecy. The New Deal of the 1930s brought on a great increase in government regulation, along with a great range of concern. In 1938, Roscoe Pound—then chairman of the American Bar Association’s Special Committee on Administrative Law and former Dean of the Harvard Law School—denounced what he saw as turning “the administration of justice over to administrative absolutism...a Marxian idea.”¹ Dean Acheson was enlisted by the Roosevelt administration to address the matter. In 1946 the Administrative Procedure Act was enacted with its provisions for discovery, due process, and the like. As early as 1935, the Federal Register had been established to publish all public regulations. President Carter even decreed that his cabinet members actually read all such decrees issued by their departments, although one by one they begged off. The task was too great. Still this regulatory regime answers to most democratic standards.

Not so secrecy. The Report of the Commission on Protecting and Reducing Government Secrecy (1997) begins:

Secrecy is a form of government regulation. Americans are familiar with the tendency to overregulate in other areas. What is different with secrecy is that the public cannot know the extent or the content of regulation.²

It remains a hidden, enormous, metastasizing mass within government itself. In a recent paper entitled, “On Liberty, the Right to Know, and

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Public Discourse: The Role of Transparency in Public Life,” economist Joseph Stiglitz argues:

There is, in democratic societies, a basic right to know, be to informed about what the government is doing and why. To put it baldly, I will argue that there should be a strong presumption in favor of transparency and openness in government. The scourges of secrecy during the past seventy years are well known - in country after country, it is the secret police that has engaged in the most egregious violations of human rights. I want to talk today about the kind of secrecy that is pervasive today in many democratic societies. Let me be clear: this secrecy is a far cry from that pursued by the totalitarian states that have marred the century that is drawing to a close. Yet this secrecy is corrosive: it is antithetical to democratic values, and it undermines democratic processes. It is based on a mistrust between those governing and those governed; and at the same time, it exacerbates that mistrust.³

Stiglitz’s paper, which was presented at Oxford, followed the 1997 Report of the Commission on Protecting and Reducing Government Secrecy. (The Commission is a statutory body with members of both parties, both houses of Congress, and representatives of the Executive.) Although less elegantly stated, the unanimous conclusions and recommendations of the Commission were not that different. In 1998, the Senate Committee on Governmental Affairs unanimously supported the Government Secrecy Reform Act, a bill based on the Commission’s recommendations. Now we have this colloquium sponsored by the American Association for the Advancement of Science and the Massachusetts Institute of Technology, a momentous academic initiative.

In all, we may hope that a new subject has appeared—or rather, reappeared. Almost half a century ago in 1956, Edward Shils, recently described as “the most learned man in the social sciences” of his time, published *The Torment of Secrecy*, an impassioned yet rigorous account of the turmoil of the McCarthy era of the 1950s.⁴ As the turmoil was just then subsiding, Shils wrote, “A great society should not allow its partial recovery from a humiliating and unjustifiable lapse from decent conduct to diminish the necessity for the conscientious scrutiny of that lapse.”⁵

Seymour Martin Lipset—fearless as ever—observed that at the height of anti-Communist fervor, loyalty oaths, and the like, a person could get in more trouble on the principal American campuses by supporting

McCarthy rather than opposing him. But that would scarcely have included Shils. In the 1930s, he had made clear his contempt for fellow travelers: “the rush of the Gadarene intellectuals” to embrace Communism. Wartime service in the Office of Strategic Services only strengthened his disdain, adding an element of concern. In *Torment* he writes:

The Communist Party of the United States is and has been malevolent in intent. Its impotence as an effective conspiratorial revolutionary body does not mean that it is entirely harmless. Given the interest of the Soviet Union in penetrating such information on American resources and intentions as are kept secret, and given the subservience of the Communist Party to the Soviet Union, there have been ample grounds for care in dealing with Communists or persons under their influence.

He was, however, a cofounder of *The Bulletin of the Atomic Scientists*. He continued:

The scientists, who had worked on the bomb and knew its monstrous powers, felt perhaps more than a little guilty over their role in having produced this necessary tool of destruction and they also knew enough about the inner nature of science and scientists to foresee that the American monopoly of the scientific and technological knowledge which went into the making of the bomb could not be indefinitely maintained.

They hoped for some mode of international control. But before anything could be achieved, the Soviet Union detonated its own bomb and the Cold War was on. Soon came some evidence and many charges that they had stolen the secret. Again, Shils:

The American visage began to cloud over. Secrets were to become our chief reliance just when it was becoming more and more evident that the Soviet Union had long maintained an active apparatus for espionage in the United States. For a country that had never previously thought of itself as an object of systematic espionage by foreign powers, it was unsettling.

The atomic bomb was a bridge over which the fantasies ordinarily confined to restricted sections of the population—hole-and-corner nativist radicalism, religious fundamentalism, and revolutionary populism—entered the larger society which was facing an unprecedented

threat to its continuance. The fantasies of apocalyptic visionaries now claimed the respectability of being a reasonable interpretation of the real situation.

Shils called for a “functional secrecy” that would protect the society from “genuine external danger.” What he feared was secrecy that was not functional, but symbolic.

Part of the war of fantasy which the pure and good conduct incessantly with corruption and evil until the Last Judgment. The secrecy demanded by ideological extremism in the United States and in Soviet Russia, in Soviet China and in the Soviet satellites is not connected with national security except by the occasion which crises provide for fanatics to focus their excited fantasies.⁶

What Shils did not know—something none of us knew until John M. Deutch, in his role as Director of Central Intelligence and a member of the Secrecy Commission, made the archive public—was that the United States had by then intercepted and decrypted the text of Soviet cables going back to World War II (the VENONA project). The first such cable was broken on December 20, 1946 by Meredith Gardener in Arlington Hall, a requisitioned girls’ school not far from the Pentagon. It contained a list of the principal scientists at Los Alamos. Looking over Gardener’s shoulder was William W. Weisband, an Army corporal, cipher clerk, and spy. By the time Shils published in 1956, the United States military and law enforcement agencies knew all about the Soviet attack—or all that they needed to know—and had pretty much rolled up the entire operation.

The Soviets knew this, as did the United States Army and the FBI. Further, they knew that the Soviets knew and that we knew they knew. Only the American people did not know—including, it would appear, the American President, this on the direct orders of Omar Nelson Bradley, Chairman of the Joint Chiefs of Staff, recorded in an FBI memorandum dated October 18, 1949. If the President was to know, the General would inform him—which, evidently, he did not.

Had Shils known this, he likely would have instantly recognized the rise of bureaucracy as propounded by Max Weber in Germany in 1922.

The pure interest of the bureaucracy in power, however, is efficacious far beyond those areas where *purely functional* interests make for secrecy. The concept of the “official secret” is the specific invention of bureaucracy, and nothing is so fanatically defended by the bureaucracy as this attitude, which cannot be substantially jus-

tified beyond these specifically qualified areas. In facing a parliament, the bureaucracy, out of a sure power instinct, fights every attempt of the parliament to gain knowledge by means of its own experts or from interest groups. The so-called right of parliamentary investigation is one of the means by which parliament seeks such knowledge. Bureaucracy naturally welcomes a poorly informed and hence a powerless parliament—at least in so far as ignorance somehow agrees with the bureaucracy’s interests (*italics added: see Shils’ term “functional secrecy”*).⁷

Note that of the 6,610,154 secrets created in 1997, a small proportion (some 1.4 percent) were created under statute—that is to say, the Atomic Energy Act.⁸ The remainder are pure creatures of bureaucracy via Executive Orders.

The proposition that President Truman was never told of the VENONA decryptions has been challenged.⁹ As it ought, for the thought is discouraging. Yet for whatever small increment of confidence that might attach, let me say that I suspected Truman had not been briefed, and was sure if we dug deep enough we would find evidence—as we did, hence the proposition. This was Army property, and the Army commander would not part with it save in exchange for something of equal value, which evidently never materialized.

Stiglitz has now added an economist’s perspective: there are gains to be got.

Secrecy provides some insulation against being accused of making a mistake. If a policy fails to produce desired results, government officials can always claim that matters would have been even worse but for the government policy. While we all recognize human fallibility, government officials seem particularly loath to own up to it, and for good reason: the public judges mistakes harshly. But there is a vicious circle: given that so little information is disclosed, the public must rely on results in judging government officials. The officials receive credit for good results, whether they deserve the credit or not; and they are condemned for bad results. ...

If outsiders have less information, voters may feel less confident that they will be able to take over management effectively. Indeed, the lack of information of outsiders does increase the costs of transition, and make it more expensive (for society) to change management teams. The fact that the alternative management teams

have less information means that there is a higher probability of any proposals that they put forward will be ill-suited to the situation. By increasing the mean cost of transition and increasing the subjective variance, secrecy puts incumbents at a distinct advantage over rivals.¹⁰

Thus the military might well have asked what the public would think if it were known that all those spies got into and out of Los Alamos—a Corps of Engineers project, after all.

Stiglitz offers another economist's insight:

While it may be in the interests of the government as a whole to maintain secrecy, it may not be in the interests of particular individuals. Indeed, that is what gives rise to the whole problem of leaks. As in the case of other forms of collusive behavior, there are incentives for individuals to deviate. If a secret is shared among a number of individuals, any one of the individuals can reap the scarcity rents for himself by disclosing the information to the press.¹¹

Is it not likely that something similar is going on right now regarding Chinese doings at Los Alamos? Such information that we evidently have is classified. Yet it continues to leak, to the presumed advantage of various parties. Once again, a foreign government probably knows, the American government sort of knows, and the American public only knows what is given without attribution to the press. This is not what an economist would call transparency.

A similar situation occurred in 1976 when President Ford approved a "competitive analysis" of Soviet strategic strength and intentions.¹² As related by Christopher Andrew, a "B Team" of conservative critics of the CIA's supposed "arms control bias" was asked to make an independent analysis of the Agency's view, which would in turn be critiqued by an in-house "A Team." The B Team concluded that the Nation was in grave peril given the Soviet "drive for dominance." The classified B Team report was delivered December 2, 1976. "Within a few weeks the main conclusions of the report had been leaked to the press."¹³ Ronald Reagan, for one, was convinced, and upon his becoming President four years later the B Team was well rewarded both in policy terms and appointments.

I had been a member of President Ford's cabinet, having returned from a posting in India more than ever convinced of the power of ethnicity in

world affairs. Colonial empires did not last. On my way home from visiting China I wrote a “Letter from Peking” for *The New Yorker*, which concluded that that regime would be around for a bit, as would the Soviet Union “until ethnicity breaks it up.”¹⁴ By 1979, in *Newsweek* I proposed that the break-up would come in the 1980s. But the B Team had access to classified information and hence far greater authority, although, one could argue, the analysis was incomplete.

This brings us to a final thesis in what I dare to call the science of secrecy. In *The Torment of Secrecy*, Shils wrote that the “American visage began to cloud over” when we learned of Soviet espionage. “For a country that had never previously thought of itself as an object of systematic espionage by foreign powers, it was upsetting.”¹⁵ Shils, a second-generation American, was seemingly little aware of the near panic over German espionage that accompanied World War I. The Espionage Act of 1917. Theodore Roosevelt going on about the “Hun within our own gates.” Eugene V. Debs going to prison. The German language and culture, beaten down—even to the lowest of dogs (in 1919 at the Westminster Kennel Club Dog Show, Dachshunds were entered as Badger Hounds).

Espionage is almost invariably associated with diaspora politics. It can lead to panic, as with Germans in the First World War or Japanese in the Second. On the other hand, the atomic spies were in the main first- or second-generation Central Europeans. Little was made of this. Chinese will now be watched a bit more closely, as might Indian nationals. But American society has pretty much lost its nativist dread—not enough natives, or so I would hypothesize.

Again to the matter of routinization. If the Department of Energy was insufficiently alert to the goings on at Los Alamos in the 1980s, there is a possible explanation. It was trying to determine whether Glenn Seaborg was seeking to give classified secrets to the Library of Congress. Dr. Seaborg kept a journal during his years (1961–1971) as Chairman of the Atomic Energy Commission (AEC). A lifelong practice. On leaving the AEC he had his journal checked out by their Division of Classification, which approved it and sent it on to his office in Berkeley. In 1983, he lent a copy to an historian in the Department of Energy, a successor agency. In 1985, he was informed that the journal contained classified material and would have to be reviewed. Threatened with arrest—literally—he turned it over. Agents by the dozen went through the 35.4-linear-foot document. Back it came, black and blue as you

might say. Thus one previously classified and now declassified entry for “Tuesday, October 31, 1961”:

I took Dianne, Steve, Eric, and Dave on a Trick or Treat jaunt around the neighborhood on this Halloween evening.

This is not so absurd as it may appear. The entry for that day begins recounting a conversation with Jerome Wiesner about an “FAS” letter about reopening the Oppenheimer case. “Jerry Wiesner said he had talked with legal people about this problem and he also had talked to McGeorge Bundy and their combined feeling is that in the present climate the President would be embarrassed if the case were opened.”¹⁶ He went on to recount discussions of atmospheric testing. (The Test Ban Treaty was in the offing.) “We think the only thing to do is to announce publicly that we are preparing. Jerry said he wasn’t sure we should do that... .” President Kennedy had given approval, “despite objections from State and Defense,” to issuing a fact sheet on the “Effects of 5, 10, 20, 30, 50 and 100 MT weapons... .” He had called the Secretary of Defense and the Acting Secretary of State to explain “why AEC feels that the public should have this information.” A quarter of a century later the Department reacted to all this, classifying the entire page—including the Halloween passage—evidently not noting that the subject had changed. We call this routinization.¹⁷

Seaborg wrote all about this in “Secrecy Runs Amok,” an article that appeared in *Science* in 1994. “With the beginning of the Reagan administration, the government had begun to take a new, more severe and rigid position with regard to secrecy.”¹⁸

In 1997, he came to see me. I drafted legislation that would return the journal unredacted. The Clinton administration’s Department of Energy said this could not be allowed. “The Department...has treaty and statutory responsibilities under the Non-Proliferation Treaty and the Atomic Energy Act of 1954, as amended, to protect national security and proliferation equities.”¹⁹ Whereupon the measure failed. I am trying again, but with modest hope, at best.

I return to the thesis that organizations behave in this manner—Cabinet departments; not, perhaps, relatively young commissions. Thus, Seaborg was willing to help get Oppenheimer free of animus that developed when “the American visage clouded over.” No Cabinet secretary would risk that. (Nor, yet, did the Kennedy White House).

Science has fought back, insisting on a balance. From the beginning of the atomic age physicists have insisted there were no secrets in nature—nor, for long, in technology. As such, there is inherent tension over government control of scientific communications. As Harold Relyea of the Library of Congress has summarized in *Silencing Secrecy*:

To the extent that national security restrictions were selective and limited, they were not regarded as a danger to achievement and progress in science and technology... . Controversy arose over whether or not actual conditions warranted or justified increased national security controls, as well as over the breadth of the new restrictions, and their seemingly adverse impact on achievement and progress in science and technology in the United States.²⁰

The definitive statement was made by a task force convened by the Defense Science Board in 1970. The task force was headed by Frederick Seitz of the Rockefeller University, and among its members were notables such as Edward Teller and our own Jack P. Ruina.²¹ The group deemed it unlikely that any classified material would remain secret for as long as five years, and more likely, one year owing to “independent discovery” or clandestine disclosure. “More might be gained than lost if our nation were to adopt—unilaterally if necessary—a policy of complete openness.”²² This is the very opposite of the “born classified” rules of the bureaucratizing atomic laboratories. They proposed a “rigid schedule” of declassification, with a general period of one to five years with exemptions for specific categories.²³

The task force was formed during the Nixon administration, with the estimable Melvin R. Laird as Secretary of Defense. The very next year the same administration attempted to prevent the publication of *The Pentagon Papers*, as they came to be known—a history of United States involvement in Vietnam prepared by the RAND Corporation for the Defense Department. Secrecy took a terrible toll on the Presidency. I had been a member of the Nixon cabinet, but was now departed. What I write is conjecture, and should be considered with a measure of caution as no one has yet advanced the proposition. But let us have at it.

At the start of World War I, in the face of proclaimed American neutrality, Germany set upon a campaign of espionage aimed at curtailing the American supply of armaments for the Allies. These activities were relatively minor—though they did manage an enormous explosion of the munitions facility on Black Tom Island in 1916—but the perception

of conspiracies and foreign intrigues attended the anxieties of state. Normally moderate, reasonable men and women would grow hysterical confronting unnamed, unseen, and frequently nonexistent dangers. War brought revolution, which brought more war, and then more revolution. Reflexively, the state prepared to guard itself “against all enemies whether domestic or foreign.”

Thus, on June 3, 1916 (ten months before the United States would enter the war), the Wilson administration submitted 17 separate bills to Congress to protect the country, as President Wilson warned, from “citizens of the United States...who have poured the poison of disloyalty into the very arteries of our national life.”²⁴ One bill called for prior restraint of the press, a lawyerly term for censorship. On April 2, 1917, President Wilson asked a joint session of Congress for a declaration of war against Germany. On the same day, House Judiciary Committee Chairman Edwin Yates Webb (D-NC) introduced an omnibus bill along the lines of the 17 administration bills. Senator Charles A. Culberson (D-TX) introduced a similar bill in the Senate. Although at first receptive to the censorship measure, on second thought Henry Cabot Lodge, Majority Leader of the Senate, decided it would not do and so stated on the Senate floor. (See *Congressional Record*, May 14, 1917.)²⁵ President Wilson sent a letter to Webb (the House having passed the measure by a vote of 191 ayes, 185 nays, 1 “present,” and 54 not voting)²⁶ pleading his position. Thus:

Authority to exercise censorship over the press to the extent that that censorship is embodied in the recent action of the House of Representatives is absolutely necessary to the public safety...I want to say again that it seems to me imperative that powers of this sort should be granted.²⁷

Nevertheless, the conferees rejected the provision and the measure was thus not included in the omnibus Espionage Act of 1917. A half century later this incident had seemingly vanished from the government’s memory. Secrecy was so pervasive that it was simply assumed that government could prevent the publication of the glum compilation. The President’s lawyers argued the “inherent power” of the Presidency, with no seeming awareness that a previous President had deemed a law to be necessary and that the Congress had openly and emphatically decided to make no such law. A divided Supreme Court upheld *The New York Times* and *The Washington Post’s* right to publish, but mostly on general principles of freedom of the press.

Justice Stewart went on to write memorably that “moral, political, and practical considerations would dictate that a very first principle... would be an insistence upon avoiding secrecy for its own sake. For when everything is classified, then nothing is classified, and the system becomes one to be disregarded by the cynical or the careless, to be manipulated by those intent on self-protection of self-promotion.”²⁸

It should be noted, however, that Justices Marshall and Douglas (Justice Black concurring), and Justice White (Justice Stewart concurring) all took note of the rejection by the Senate of President Wilson’s legislation calling for prior restraint. It was all there in the law library. But the memory had disappeared from the Executive. After the decision, the “Plumbers” were formed to prevent further leaks. The downward spiral commenced, and in time Nixon, faced with impeachment, became the first President in our history to resign.

Iran-Contra was next, a dozen years later. An administration obsessed with the threat of a Communist coming to power in a Central American country set out to support a counterinsurgency. In time the CIA laid mines in Pacific Coast harbors. The Senate Select Committee, of which I was then vice chairman, was not told, despite a statutory provision requiring that the Committee be kept “fully and currently informed of all intelligence activities.”²⁹

Faced with these facts, the Director of the CIA lied, I resigned. A handsome apology did follow, but the Administration now secretly turned to Iran, trading weapons for money to support the Contras. It all came out. The President escaped—it is not at all clear how much he knew—but the Presidency had once more been put in harm’s way. In his account of the crisis, Theodore Draper writes: “If ever the constitutional democracy of the United States is overthrown, we now have a better idea of how this is likely to be done.”³⁰

My closing note is on the legislation proposed by the Secrecy Commission. A bipartisan bill requiring that an official who makes the decision to classify information shall identify himself or herself and provide written justification for the action; a presumed ten-year limit on classified material with an extension procedure; and a more systematic declassification system was unanimously passed out of the Governmental Affairs Committee in 1998. The Administration, however, could not accept the prospect of judicial review of classification decisions. A new

bill has been introduced in the new Congress—nothing exciting here, but we may have entered a period the old Marxists would have described as “demystification,” or the revelation of underlying interests. Shils might not have disagreed. Presidents take note.

Endnotes

1. Daniel Patrick Moynihan, *Secrecy: The American Experience* (New Haven: Yale University Press, 1998), p. 157 from Roscoe Pound, quoted in *Annual Report of the American Bar Association* 63 (1938): 340.
2. Commission on Protecting and Reducing Government Secrecy, *Secrecy: Report of the Commission on Protecting and Reducing Government Secrecy* (Washington, DC: Government Printing Office, 1997), p. xxi.
3. Joseph Stiglitz, 1999 Oxford University Amnesty International Lecture, Oxford University, January 27, 1999 (transcript available at www.worldbank.org).
4. Donald Dewey, “Edward Shils: A Last Harvest,” *Society* 36 (March/April 1999), no. 3:75.
5. Daniel Patrick Moynihan, introduction to Edward A. Shils, *The Torment of Secrecy: The Background and Consequences of American Security Policies* (1956; reprint, Chicago: Ivan R. Dee, 1996), p. xii.
6. *Ibid.*, p. xviii.
7. Max Weber, “Bureaucracy,” in *Essays in Sociology*, translated and edited by H.H. Gerth and C. Wright Mills (New York: Oxford University Press, 1946), pp. 233–34; *Wirtschaft und Gesellschaft (Economy and Society)*, 1922. Donald Dewey describes Shils’ introduction to Weber and the German tradition in sociology as “close to a religious experience.” Donald Dewey, “Edward Shils: A Last Harvest,” *Society* 36 (March/April 1999), no. 3:74.
8. The Department of Energy reports that it classified 900,000 pages of material in FY 1997 pursuant to the Atomic Energy Act. The Information Security Oversight Office reports 6,520,154 classification actions in FY 1997 pursuant to Executive Order 12958. In comparing these figures, an average of 10 pages per document is assumed, resulting in an estimated 90,000 classification decision by the DOE: 1.4 percent of the combined DOE/ISOO classification decisions reported in 1997. (Sources: Information Security Oversight Office, *1997 Report to the President* (Washington, D.C.: Information Security Oversight Office, 1996), p. 25; A. Bryan Siebert, Director, Office of Declassification, Department of Energy to Steven Garfinkel, Director, Information Security Oversight Office, National Archives and Records Administration, Washington, December 3, 1998.)
9. Richard Perle, “In the Dark,” *Commentary* 106 (December 1998), no. 6:78.
10. Joseph Stiglitz, 1999 Oxford University Amnesty International Lecture, Oxford University, January 27, 1999 (transcript available at www.worldbank.org).
11. *Ibid.*

12. Christopher Andrew, *For the President's Eyes Only: Secret Intelligence and the American Presidency from Washington to Bush* (New York: HarperPerennial, 1996), p. 423.
13. *Ibid.*, p. 424
14. Daniel Patrick Moynihan, "Letter from Peking," January 26, 1975, accepted for publication in the *New Yorker* but withdrawn after Moynihan's nomination to the United Nations.
15. Moynihan, *The Torment of Secrecy*, p. xvi.
16. Glenn T. Seaborg, journal entry, October 31, 1961.
17. *Ibid.*
18. Glenn T. Seaborg, "Secrecy Runs Amok," *Science* 264 (3 June 1994): 1410.
19. Kenneth E. Baker, Acting Director, Office of Nonproliferation and National Security, Department of Energy to Senator Daniel Patrick Moynihan, Washington, October 29, 1997.
20. Harold C. Relyea, *Silencing Science: National Security Controls and Scientific Communication* (New Jersey: Ablex Publishing Corporation, 1994), p. 6.
21. Defense Science Board, *Final Report of the Defense Science Board Task Force on Secrecy* (July 1, 1970).
22. *Ibid.*
23. *Ibid.*
24. Woodrow Wilson, "Annual Message from the State of the Union," December 7, 1915, in *The Papers of Woodrow Wilson*, edited by Arthur S. Link (Princeton, NJ: Princeton University Press, 1980), 35:306-7.
25. *Congressional Record* 55, pt. 3:2262 (May 14, 1917).
26. *Ibid.*, pt. 2:1819 (May 4, 1917).
27. *Ibid.*, pt. 3:3144 (May 31, 1917).
28. *New York Times Co. v. United States*, 403 U.S. 713 (1971).
29. *Intelligence Authorization Act for Fiscal Year 1981*, U.S. Code, vol. 94, sec. 413 (1980).
30. Theodore Draper, "Getting Irangate Straight," *New York Review of Books*, 8 October 1987, p. 47.

26 Government Policy and the Commercial Value of Academic Information

Robert Cook-Deegan

We all think innovation is important—whether it is biomedical research to discover things that save people’s lives, microcomputers to do the myriad tasks we now delegate to computers, or telecommunication and transportation that make the world smaller and more tightly knit. Innovation can be a good thing—but it is not without cost. This article addresses one of those costs—the cost of secrecy. In our competitive world, innovative ideas and, often, the development of new products and technologies may be cloaked in secrecy. While such secrecy might indeed protect the initiator’s bottom line, does it have a negative impact on society as a whole? In other words, does secrecy become sludge in the scientific pipeline?

Innovation is connected to parts of the economy that grow the fastest. Two factors strongly influence the pace of innovation. One is the level of resource deployment, or how many resources are going into the process of innovation. The other is the speed of information flow in that process. As a backdrop for this discussion of secrecy in science, I would like to illustrate the dramatic expansion of scale in research and development (R&D) that has occurred in the post-World War II period.

My own areas are health policy and health research policy, areas in which there are two general attitudes about secrecy:

- when lives are at stake, secrecy is wrong—because health research is about saving lives, not making money; and
- secrecy may harm innovation.

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The first, instinctual, response is that there should be no secrecy, because “if there are lives at stake, of course it is a very bad thing.” This is a widely held attitude, and it will continue to be reflected in public opinion surveys. Federal policy, however, is not premised on that response. In fact, a lot of our policies create incentives to keep secrets for certain periods of time, because we believe that there is some connection between innovation and being able to keep and protect information that is commercially valuable. The policies are driven by a belief that in the long run, we are all better off if some people can protect information for limited periods. I will not further examine the “all secrecy is bad” stance, but will make the case that even if viewed from the narrower framework of the national system of innovation, and on efficiency grounds alone, secrecy can be sludge in the pipeline of innovation.

Anybody who talks about innovation these days has to disavow the pipeline model of innovation. We no longer believe in a simple pipeline model, if we ever did. The pipeline model was developed some time ago and was probably most beautifully laid out in the first few annual reports (in the early 1950s) of the National Science Foundation. The model says that the innovation process begins with basic research, then moves to applied research, then to development, then to application of that development, and then marketing of a product. The notion was that the process entails a flow from step to step—that basic science begets applied research, which then begets development and then, eventually, a product or service. In this model, federal funding for basic research passes the baton to industrial support for development.

There are kernels of truth to the model, if we step back far enough and review a long enough time span. The most apparent one is that in general, the flow is indeed from science toward the market through development. But the flow is far from uniform—there are many eddy currents and reverse flows, and the feedback system is a paragon of cybernetic complexity. Perhaps the key insight of the past few decades is that what is being mapped is not the flow of ideas or widgets, but of people and information—not all people, but those carrying a stock of tacit knowledge about how to do new things.

Another kernel of truth to this model is that in terms of investment in R&D, the public and private sectors are curiously mismatched partners who are intertwined in a delicate dance. While most private R&D is product- or service-oriented, public R&D is typically mission-oriented (e.g., health, defense, and space exploration). And yet, public science induces private investment, and private science induces public R&D.

From the end of World War II until today, life sciences research has grown enormously, most markedly through the National Institutes of Health. The federal government has become deeply involved in the complex ecosystem that supports innovation, and during the 1980s and 1990s, federal R&D funding has become increasingly skewed in the direction of the life sciences, especially biomedical research. (Figure 1 and 2)

Few people realize that the United States is unique in its emphasis on health in terms of its R&D priorities. The U.S. spends more on health research as a fraction of its gross domestic product (GDP) than any other country. Since we have the largest GDP in the world, we have a huge investment in health research compared to any other nation. The relative funding in engineering, chemistry, or physics is quite different, as other countries have a higher fraction of their GDPs devoted to these sciences than does the U.S. (Figure 3)

This is also the case with private investment. To illustrate this trend, I will use R&D spending by members of the Pharmaceutical Research and Manufacturers Association (PhRMA). Sometime in the late 1980s or early 1990s, private annual investment in R&D in the health sector exceeded the federal investment. So the rate of growth in private funding has been even greater than in government, and more private money than public money is now going into health R&D. (Figure 4)

We now face situations that are analogous to situations that confronted computing research in the 1960s and 1970s. For example, consider the policy pursued by the Defense Advanced Research Projects Agency (DARPA) regarding chip design. DARPA is a part of the Department of Defense that funds research for all of the armed services. It was created in the wake of Sputnik. Staff at DARPA identified very large scale integrated circuits—that is, the chips we now take for granted—as being important to the future of microelectronics. They identified chip-making as a critical technology. Chip manufacturing was capital intensive; therefore, private firms were doing most of the work. (An analogous situation exists in the genomics R&D environment: the private sector is generating data and technology; competition limits data sharing, standard setting, and academic collaboration; and lead firms seek to protect themselves from harm resulting from information flow.)

Each firm was trying to develop a chip that nobody else could use in order to lock customers into their line of products. As a result, many products were incompatible. What we now take for granted as stan-

Figure 1
The Lasker Legacy: NIH's Postwar Growth

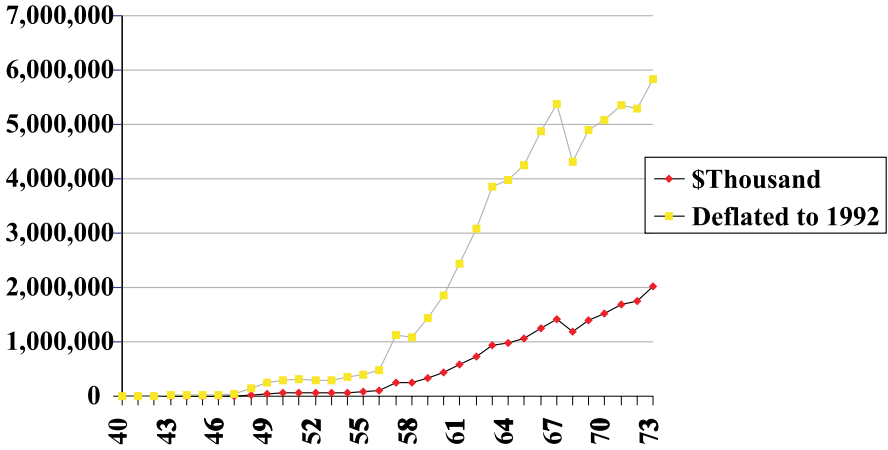


Figure 2
Research Funding
 (Adjusted to 1992 Dollars)

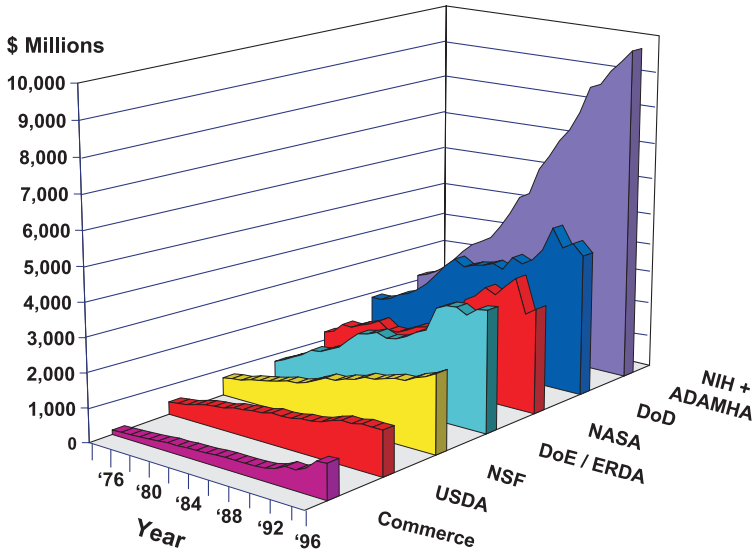
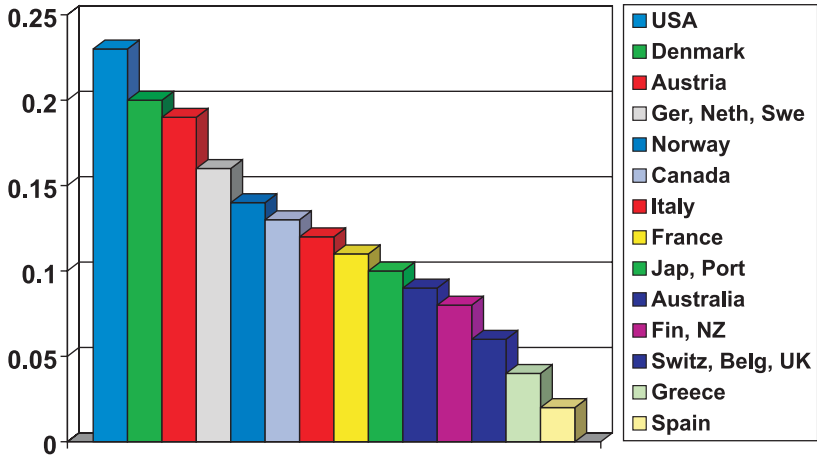
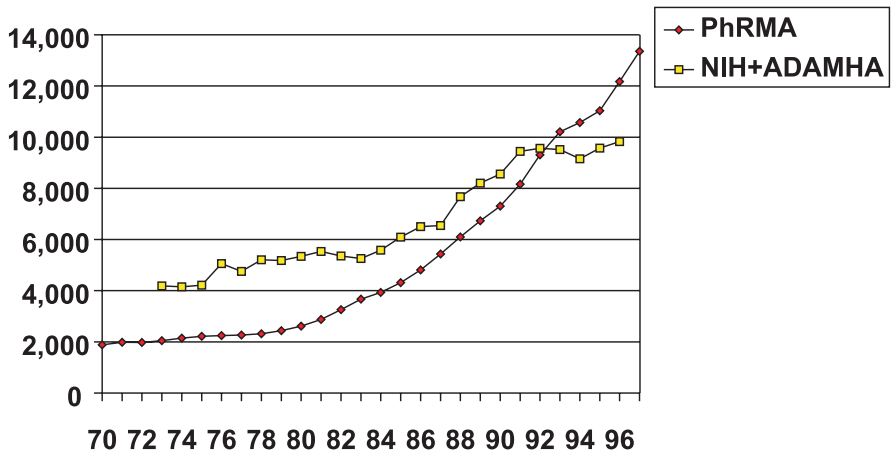


Figure 3
Health R&D as %GDP



Sources: Michaud and Murray, Harvard School of Public Health.

Figure 4
Private R&D Exceeds Public



Sources: NSF FFRD Survey; PhRMA Annual Survey, 1997; ADAMHA 1992 (corrected)

standard operating systems were not yet developed, and if the trend had continued, they never would have been. It was not clear in that framework—where most of the R&D took place in private sector silos—whether products would be mutually compatible or who would design chips in the future (since few graduate students were being trained). DARPA decided that there was a serious choke point that endangered the future of integrated circuit design. What they pursued as a partial solution was a research program strategically placed in academic institutions. It was an attempt, among other things, to supply academic groups to keep up with cutting-edge research in chip design.

DARPA did two basic things. It funded researchers who were then linked to graduate students and formed an academic network. They also funded a fabrication facility to which graduate students or academic researchers could send a design over the Internet (the ARPANet in those days). It was a way to lower the barriers to innovation in design, allowing a large number of people from different institutions to say, “Please make this chip, send it back to me, and I will see how well it works.” No single university would have been able to support that, but with a chip fabrication facility available to all universities, it became possible for chip design work to be rather open. Another important indirect result of the DARPA initiative was a textbook (written by professors Carver Mead and Lynn Conway) that served as a rule set and guiding principles for chip design. The textbook allowed an exchange of information and informal adoption of standards that was not happening under the proprietary model.

Why did DARPA pick universities? Partly because there is a strong presumption at universities that research will result in information that is openly published. In addition, universities house cheap, highly expert labor. Graduate students are underpaid, and in a fiscal production model that is a good thing. That source of cheap labor is also leveraged into the future because the research program trains people who are going to be company managers and designers of future chips. Universities have two other effects on the innovation ecosystem. One is that if the work is openly published, it is available to all firms in a way that if the work was done at a single firm and not published, it would not be. Much industrial research remains unpublished, even in biomedicine, where publishing is respected in the biotechnology and pharmaceutical firms. The wide availability of information to diverse firms is not a universal rule, but in general, research is more available if it is performed in the academic sector. Moreover, it is usually a lot easier for academic groups

to collaborate with industrial partners of different sizes and levels of sophistication. So the research done in universities is valuable to many firms.

The grander scale of R&D and the direct relevance of R&D to practical application have led to many changes in the university. One is that universities now seek patents to a greater degree. That has led some universities to see technology licensing primarily as a profit center, or business operation, of the university. In the postwar era there was an active debate in the major universities that pitted the federal government against industrial research. For example, the Stanford Research Institute was created to produce direct industrial investment in order to keep the university from having to depend on another unreliable partner—the federal government. In many sectors there was an either/or framework for industrial research funding.

The most successful major research universities figured out that the winning strategy was to use federal funding as the base and use industrial funding to augment (but not supplant) that base. The strategy that has worked seemingly over and over in field after field is to create a cadre of highly conspicuous, well-known scientists who publish frequently and become known not only to their scientist colleagues but also to firms working in that area. These stars are the people who are going to attract industrial funding. They are also going to get patents and publish the most. The origins of biotechnology, it has been well documented, grew from a star system in molecular biology, and every university administrator has come to recognize that. Finally, it has become abundantly obvious that the enormous sums of federal R&D money create a mountain of information that can be mined by private firms for valuable applications. Building mountains of knowledge is a big part of what universities do these days.

Turning now to secrecy, in her book *Regional Advantage*, AnnaLee Saxenian compares the MIT Route 128 region with Silicon Valley and looks specifically at the early 1980s, when there was a depression in the computing industry. She found that recovery in Silicon Valley was much faster than it was along Route 128. She ascribed it to the way the firms behaved and the way individuals behaved within those firms. She observed that in Boston people tended to be loyal to a single firm. Those firms tended to be relatively insular, and workers focused on job stability. In contrast, within Silicon Valley the loyalty was to the technology more than the firm. Companies like Hewlett-Packard and Fairchild thought spin-offs were cool, not something to be fought. In Massachusetts,

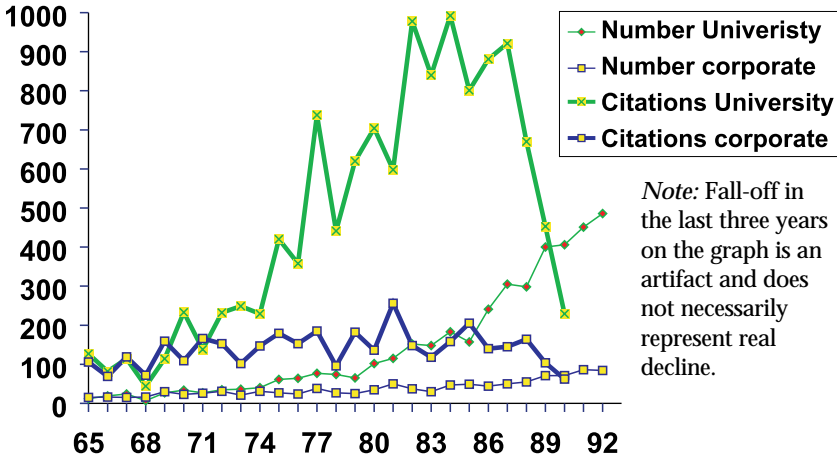
when Data General split from DEC, there was a bitter battle with lingering memories. Across the country, Hewlett-Packard and Fairchild were comfortable with their employees starting new companies, and Hewlett-Packard invested heavily in the local community well beyond its immediate business interests.

Those are the principal reasons Saxenian used to explain why Silicon Valley was quicker to recover than Route 128. Another part of the equation, however, is secrecy. Saxenian did not focus on this as much, but I believe it can explain some of the difference as well. The research ethos in the Boston area was heavily influenced by work in the wartime era. Wartime research was big at Stanford, too, but it not nearly as big or dominant. The prototypical institution at MIT was the Lincoln Labs, and in Stanford it was the linear accelerator. The ethos of those two institutions was very different. A significant difference was in the degree of information sharing. Most of the work at Lincoln Labs was secret, and that secrecy was strongly enforced. The linear accelerator facility was mainly a tool for open research. Communication was much more open on the West Coast.

That said, why should we care about information sharing? Two points about biotech illustrate that the rules about secrecy and patenting intellectual property may play out differently in biotech than they have for other technologies. First, patents matter more in pharmaceuticals and biotech than they do in any other major sector of the economy. Pharmaceutical firms routinely invest ten years in developing a lead compound and bringing it to market. The reason they can do that is because they can rely on strong patent protection that will survive that whole period of investment. In contrast, telecommunications and software firms do not rely on patents to nearly the same degree because their product cycle and time horizon for investment are considerably shorter.

The other thing that is distinctive about biotech is that it grew out of and is much more highly dependent on academic research than are other sectors. The most straightforward evidence in support of this comes from Edwin Mansfield's surveys. He asked CEOs, "How important is academic research to your business?" He asked people in telecommunications, pharmaceuticals, and other sectors. People in pharmaceuticals routinely reported that about one-fourth of their products depended completely at some point on academic research and another fourth would have been delayed significantly without a base of NIH-supported academic research. In most other sectors, CEOs reported figures that were half that or less—a twofold higher dependency on academic research in pharmaceuticals compared to other sectors.

Figure 5
Drug/Medical Patents



Source: "Universities as a source of commercial technology: a detailed analysis of university patenting, 1965-1988," Rebecca Henderson, Adam Jaffe and Manuel Trajtenberg, Review of Economics and Statistics.

Econometric studies corroborate those surveys, correlating the number of patents, citations, ownership of patents, and other measures. A much higher fraction of patents based on DNA technology, for example, is owned by academic institutions than are other kinds of patents, such as chemicals or instruments. The DNA Patent Database (at the Foundation for Genetic Medicine) indicates that among the more than 1,000 DNA patents issued between 1980 and 1993, roughly 30 percent are owned by academic institutions. The academic patent ownership rate is five percent or lower for most patent classes.

Figure 5 shows the academic and industrial patent trends for academic and industrial firms in the pharmaceutical patent classes. The line on the bottom, which represents the number of patents filed and obtained by academic institutions from 1965 to 1992, indicates a very rapid rise. Two things are worth noting here. First, the rise began before the Bayh-Dole Act was passed in 1980—the ethos had already shifted. The other is that it is not just academic patenting per se, but also a rise in the citations to academic patents. In the same publication from which these data were extracted, this high level of citation of academic patents is not evident in chemistry, telecommunications, or other areas. In fact, in the

Bayh-Dole era there have been more and more patents obtained by academic institutions, but fewer and fewer citations to them. That is the main point of the paper by Henderson and colleagues from which these data were extracted. Biotech, however, is maintaining this importance of the academic research base.

I want to use genomics as a case example to illustrate disparate approaches to promoting commercial application. There appear to be at least five business models at work in genetics research that are working simultaneously in a real-time experiment about what works best. The Human Genome Project was originally conceived as a public infrastructure project—the federal government was going to create maps and databases that would serve as an interstate highway for human genetics that would be useful to everybody. It was a government enterprise, and the idea was “Build it and they will use it.” That origin carries forth into current government genome projects. The Department of Energy (DoE) and the NIH have growing programs. Those programs include large-scale sequencing centers, the big groups that get tens of millions of dollars per year to do rapid sequencing. This approach is shared by the Wellcome Trust (which, while a private nonprofit funder, behaves similarly—or better—than government funders) and several foreign collaborators. The rule is open access and rapid disclosure of data.

In Palo Alto in 1992–1993, a firm called Incyte, which began as a Genentech contract firm, turned to sequencing expressed DNA sequences from the human genome, using sequencing as a way to grab lots of genes very quickly. They evolved a business model and became a publicly traded firm in 1993 based on plans centered on creating a database of sequences and tools to analyze it. Incyte’s basic strategy was to license access to their database to individual firms, mainly large pharmaceutical companies. The business plan has evolved, but that remains an important underlying strategy.

Another company, Human Genome Sciences (HGS), was formed in 1993. It took a similar scientific approach, but with a different business strategy. HGS initially had just one big investor, SmithKline-Beecham. HGS thus had one main licensee and also sought to forge collaborations with academic groups. This effort was somewhat circumscribed because not many academic research groups were willing to work with HGS, in part because of the strictures on disclosure that were associated with it. That brings us back to the secrecy issue.

Finally, along came the giant of the pharmaceutical business, Merck, who decided to fund the same sort of work that was going on at Incyte

and Human Genome Sciences. But Merck decided to pay Washington University in St. Louis—an academic research center—to generate the sequence and put it into the public domain immediately. Private R&D money was being used to create public domain information. A similar effort has just been announced by a consortium of pharmaceutical and biotech firms to create a public domain database of information about human genetic variation.

Celera Genomics has entered the field in the last few months, and it is planning to do massive amounts of sequencing of the entire human genome and sell access to these and other genomic data on a subscription basis. Their model is more or less the Lexis-Nexis database model. Celera currently states that it will not attempt to claim rights to future discoveries, or reach-through, when subscribers use their data to discover something valuable. Nor will they impose nondisclosure agreements beyond protections for the data in their database.

The final model, which is really not a model but a hodgepodge of disparate approaches, is based on mining the research created by thousands of academic groups at universities. Most research in molecular biology is done by people who are not employed by a company. They are working in the lab doing sequencing and mapping of genes, working at institutions whose policies regarding intellectual property are all over the map—such as licensing, speed of disclosure, and willingness to restrict publication.

Why is this happening in genomics? A few features defining genomics seem likely to generalize to many other fields. First of all, it costs a lot of money. The main thing these companies can do that academic researchers cannot is spend lots of money up front on two things—computers and sequencing machines, which are very expensive and require serious management to make them work. Companies that purchase hundreds of new sequencing machines will have the capacity to generate sequencing information much faster than any academic group can hope to match. For genomics companies and firms in other rapidly moving fields, the value of the information is when it is fresh—its commercial value decays rapidly. Its scientific value may or may not drop rapidly, but its commercial value drops very rapidly with time, because that value derives in large part from exclusivity—and a big part of exclusivity is who finds the information first.

Two features are shared by chip design and genomics. One is that the research is not basic or applied—it is both. Research creates extremely interesting information that is also extremely useful. The other sim-

ilarity is that you need lots of equipment to interpret the information—to make it meaningful. The information is so plenteous and complex that it is useful only if you can use computers to help analyze it.

Information flow problems, too, are beginning to crop up in genomics and other fields. There are several reasons that individuals may want to keep information quiet. Early in the genome debate, one of the reasons that the National Research Council did a report on mapping the human genome was a concern among molecular biologists that human geneticists were sitting on data, and hoarding pedigree and related resources. That was, in fact, true. Secrecy was not because of money and it was not because of patents or commercial interests. People who spend a lot of time creating a pedigree and putting work into constructing a clinical profile of every member of that pedigree are reluctant to share that information because it is closely linked to their ability to publish and advance their careers.

Damming information flow has been and still is a serious problem in human genetics and other areas. (In fact, one of the reasons for the Human Genome Project was to break the lock that human geneticists had on the information flow.) Information logjams typically resulted from such common practices as pursuing worldwide patents, seeking a royalty stream, signing nondisclosure agreements, and establishing licensing agreements for access to materials or information.

In the example of pursuing patent rights worldwide, individuals or institutions seeking a foreign patent cannot publicly disclose data before filing the patent application. You can get a U.S. patent, because the United States has a one-year grace period after public disclosure, but you cannot get a foreign patent if you publish first. Sometimes people will sit on data just because the data are valuable, not because they can get a patent or copyright or anything else—they just know that someone will be willing to pay for access to it.

One of the most serious information dams is the nondisclosure agreement, which is usually associated with licensing agreements for data or research materials. In this case, the investigator says “I’m not going to talk about the data pertinent to this project under the following conditions,” and those conditions are specified in the license. That is one of the social norms that changed in many fields of science over the past two decades, and in particular in biomedical research. Whereas nondisclosure used to be anathema, now it is a norm in many academic institutions.

What we have got now is a real continuum of openness, and in fact, most universities would have a continuum within them. The same variation is found in the private sector. Some firms behave a lot like universities—they are very open and encourage scientists to publish in the open literature. In fact, there is evidence that firms who behave most like academic groups and encourage more open communication do better on Wall Street and secure more patents. That is, the more they look like academic groups, the better they do in the marketplace. On the other hand, there are firms that require very rigid protections on their data and there are groups within academe that collaborate with firms that require nondisclosure of all sorts of information.

Turning to public policy, one of the most troublesome aspects of trade secrecy is when it is applied to federally funded research. Nondisclosure can cloak publicly funded science when it is based on agreements with private firms or even academic groups to secure access to data, materials, or industrial funding. Terms of the agreement can hide not only the information generated out of that specific agreement, but also related information generated through federal dollars.

I was once presented with a nondisclosure agreement that took me aback. The main criterion governing public disclosure was whether it was going to harm the business interests of a particular company. Moreover, the final arbiters to interpret those business interests were officers of the corporation. That is, it did not matter who paid for the research or why it was generated, but rather what impact it would have on the company to whose data I might gain access. That makes sense from the perspective of a company, but as public policy, it is terrible—particularly so where federally funded research is encumbered.

So what are we going to do about all this? To simplify, the faster information flows, the faster innovation happens. Thus, we are all better off. That is true for firms, too, who are collectively better off to the degree that information flows freely, but each firm has a marginal incentive to lock up information for itself. We have got a prisoner's dilemma.

What can we do at the collective level? The first thing is to think about what the federal government can do. Policy options that will likely influence the academic information flow revolve around the following:

- Federal funding mechanisms
- Model agreements and guidelines

- Collective norms and standards among universities (licensing practices)
- Bayh-Dole statute modifications
- Patent law

First, giving out dollars for research can be tied to rules about open access to the resulting information. If you get a grant from DoE or NIH to do large-scale gene sequencing, for example, you agree to disclose the information rapidly. NIH and DoE have told their major sequencing groups “If you take our money, you’re going to play by our rules.” And the rules put a premium on quick disclosure.

Government can also develop policies enabling academic scientists to use discoveries made by the private sector. One example is the recent agreement between NIH and DuPont regarding sharing of Cre-lox mice. That is an example of NIH creating a model agreement to set a norm. That model should not be used just for this particular Cre-lox technology, but it also should serve as a model for other technologies that are generated by the private sector, but are useful for the academic community.

Licensing practices are where the most productive policy changes can take place. Many of the relevant policies may well be pursued outside government—by private institutions, both in academia and industry. Policies that allow academic research with low or no fees, carefully consider reach-through and exclusive licenses, and promote research and education as well as income could go a long way toward opening up the innovation process.

Should we go back to the Bayh-Dole statute? There are existing doorways in the statute that have not been used. The government can exercise “march in” rights if a patent owner fails to commercialize a useful invention. That may or may not pertain to secrecy. There is also an “exceptional circumstances” clause that says that if the public health is at stake or other government interests are better served, then government can override the usual default that gives rights in an invention to the grantee or contractor institution.

Some of the controversies surrounding access to federally funded sequencing of pathogenic microbes might be test cases. Government could at least extract commitments to license access to the information. In the defense sector, the government occasionally reclaims intellectual property to further defense needs. The government may be driven to

consider doing the same for health. If someone makes a discovery based on government funding that would be widely useful to those holding other government grants, the Bayh-Dole framework might be modified to enable ready access. There is some talk in Washington that government Bayh-Dole rights might be extended beyond government laboratories to those who are doing federally funded research in university or even small business settings. Some lawyers believe the existing Bayh-Dole statute could be interpreted that way, while others feel that an amendment would be needed.

However, revisiting or reinterpreting the Bayh-Dole statute might not be the best solution. Perhaps the most productive way to engage these questions, at least for now, is to look at the collective practices—especially at universities, because universities are the point at which industrial and government interests collide and where rapid flow of information is most important.

A final substantive point concerns the high transaction costs of protecting information. People who handle intellectual property, especially technology licensing offices, are well aware that the costs are high. It costs about \$10,000 to get a U.S. patent—double or triple that for significant protection abroad—and it costs money to maintain those patents. In the frenzy for patenting, very few of the patents obtained are ever used. Paying for an unused patent is a poor use of resources. One option is to be more selective in deciding what to patent. At a more common and mundane level, does it really make sense for all investigators to be signing material transfer agreements for everything?

Discretion in what is subject to formal written agreements, all of which cost substantial time and money to craft, would be most welcome. Most reagents and data shared among laboratories are not worth the time, trouble, or added bureaucracy. The counterpoint is that it is difficult to know the value of a discovery soon after it is made—but are we better off with a default path that presumes high value and encumbers information transfer, or one that engages the apparatus of information protection less often? It seems likely that this is another thousand-player prisoners dilemma, where the system as a whole is better off with open disclosure—even if a few individual institutions fail to get as rich as they might.

It seems likely that the effort and cost to negotiate transfer agreements, nondisclosure agreements, and the secrecy that precedes worldwide patent applications are higher than the value of rapid information flow those processes restrict. That is one of the main messages of the June 1998 NIH report on research tools. That report is quite sensible, but

we have not come to our senses yet in the academic community. The Cohen-Boyer patent set a precedent that academic institutions in particular would do well to emulate. Admittedly, it was a patent that many lawyers thought would be invalidated if it were ever challenged, but it was never challenged—in part because Stanford and the University of California kept the price low.

Those universities did two important things. First, they did not charge academic researchers for use of the technology. Second, they kept fees low for the industrial users. The licensing agreement for that patent did set a precedent that has surfaced as a reach-through problem. Most of the quarter of a billion dollars that came to the University of California and to Stanford because of that patent came from its reach-through provision. Licensees who sold a product that used recombinant DNA, even if it was a product outside the scope of the Cohen-Boyer patent claims, agreed to pay a royalty to UC-Stanford. It was those royalty streams on products made using recombinant DNA, rather than the up-front licensing fees for use of the process and vectors, that created most of the money. So Stanford and UC created a precedent for exempting academic researchers from needing a license—a precedent that may be fading into oblivion—but the same licensing agreement also set the stage for reach-through that we are grappling with now. From the perspective of a policy analyst, it seems we have neglected the useful precedents set by Cohen-Boyer and have adopted the most troublesome one.

Standards are unstable and need careful inspection in academic patenting, especially regarding two licensing practices that should raise red flags. One is exclusive licensing and the other is reach-through. I have already addressed reach-through; the other trouble spot is exclusive licensing, which ties use of an invention to one particular firm. If that firm turns out not to be the best choice, innovation can suffer. There are times when only an exclusive license will work—for example, when a discovery is quite close to final market, such as a therapeutic pharmaceutical that needs to be proven in clinical trials. But it should be the exception and last resort rather than the default path. Neither of these practices is wrong in all circumstances, but they seriously encumber future discoveries and should be pursued only with a good deal more care than some universities have been giving them.

Finally, and perhaps most important, the notion of technology licensing offices as profit centers needs to be balanced against the traditional research and educational missions of universities. We will know that is

happening when we hear university presidents making pronouncements about technology licensing policies, and when they assert that academic norms of openness should trump short-term licensing royalties. Articulation of academic norms is probably the most important policy step that needs to be taken. There are good models in place. If you look, for example, at the mission statement for MIT's Office of Technology Licensing, it makes clear that its money-making goals are subordinate to MIT's educational and research missions. The fact is, however, that the technology licensing offices at many other institutions do not operate under this or a similar mission statement.

If there were one thing I could do to reduce the level of secrecy that can impede innovation, it would be to elevate norms of open communication of knowledge in academe, and clearly to subordinate the business interests in intellectual property management to education and research at academic institutions. It is unrealistic, and would be counterproductive, to expect private firms (especially small ones) to follow the same norms of openness, but if I have convinced you of anything, I hope it is that there is enormous value to all players—including those in industry—in having academic information flow freely.

27 New Secrecy in Science: Government-Imposed to Self-Imposed

Howard K. Schachman

During World War II and for some time following the cessation of hostilities, scientists in American institutions of higher learning were deeply involved in widespread secret research. Many universities and research institutions, which traditionally fostered the free exchange of ideas and information, were subjected to curbs from government, which seemed necessary and were readily accepted. Some graduate students were in uniform, and others had draft deferments because of their research activity. Most of the time we did not know what our colleagues were doing. The requirements for secrecy and the safeguards to impose it had a large impact on the culture and ambience of universities, and it was recognized after the war that such research and the attendant restrictions were antithetical to the openness essential in institutions of higher learning.

In using the term, "New Secrecy in Science," I refer to any type of restriction that impedes or limits the freedom to pursue research and to disseminate the results of investigations aimed at understanding natural phenomena and improving the quality of life. Thus, "new secrecy" differs from the secrecy during and after World War II, which prevented, not the actual research, but rather the discussion and release of findings derived from the research. Now we have impediments to openness in scientific investigations, the communication of results and even restrictions on certain types of research. These limitations stem from actions of government, industry, universities and the investigators themselves. Thus the title: New Secrecy: Government-Imposed to Self-Imposed.

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Research with Human Embryos, Fetal Tissue, and Stem Cells

Although government-imposed secrecy which prevented discussion of the research has been curtailed to a substantial degree and is now largely confined to special laboratories separated from universities, we in the biological field are experiencing restrictions in conducting certain types of research which many consider essential to the goal of understanding basic biological phenomena and developing tools aimed at treating human disease. Much research on human embryos and fetal tissue cannot now be funded by the National Institutes of Health. This prohibition by President Clinton in 1994, came in response to the Report of the National Institutes of Health Human Embryo Research Panel, which recommended limited use of embryos for research.^{1,2} That restriction was followed by an additional ruling by Congress so all-encompassing that NIH, in effect, could not fund any research on human embryos. Following the announcement of the cloning of adult sheep by scientists in Scotland, came another policy edict that “no federal funds shall be allocated for cloning of human beings”. The President then asked the National Bioethics Advisory Commission “to review the legal and ethical issues associated with this (cloning) technology and to report back within ninety days with recommendations”. In a very thoughtful report the Commission concluded that “it is morally unacceptable for anyone...to attempt to create a child using somatic cell nuclear transfer cloning.”³ This overall conclusion was followed by a series of recommendations including the continuation of “the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.” In recommending federal legislation to prohibit such activity, the Commission urged that there be a sunset clause to review the issue after a specified time period (three to five years) to determine whether the prohibition should be extended. In another recommendation, the Commission urged that any regulatory or legislative actions undertaken “should be carefully written so as not to interfere with other important areas of scientific research.” Unfortunately, in statements by Members of Congress and in action by some State Legislatures, the language on banning cloning has been so overly broad, imprecise and ambiguous that it can limit or restrict important research.⁴

As a consequence of these administrative and legislative actions, much research in this field, to the extent that it is going on, is confined to laboratories supported by private funds. Not only is there the risk that the research may be of lower quality than would occur with NIH funding,

but ethical guidelines and accompanying regulations are much more inadequate than would be obtained if federal funds were being used. Over the course of the past five years, this struggle in Washington has intensified and expanded to include the use of pluripotent human stem cells, for research. Early in 1999, about 70 members of the House of Representatives and seven Senators went on record in opposing a ruling that would have allowed NIH to support research on the use of human stem cells, and this contentious issue is now being debated. Following that release, many scientists and officials of professional societies dealing with biological research responded, in letters to President Clinton and Members of Congress, with the claim that there is a "moral imperative" to pursue research with human stem cells because of its potential for treating human disease.⁵ Some of those who oppose this research do so because of their concern over, and opposition to, cloning human beings. Scientists, to an overwhelming degree, join them in opposing the cloning of human beings, but we stress that those who urge restricting this research fail to differentiate between creating knowledge and applying knowledge. Whereas there could certainly be useful discussions about restricting applications of new biological techniques, it is difficult to understand how one can oppose the acquiring of knowledge. It is important to note that others, and perhaps the majority, who stridently oppose the use of stem cells have another agenda. Their opposition derives from their views on abortion and the source of the human stem cells. Moreover, they condemn the use of stem cells regardless of the source, a position which is probably not acceptable to most scientists.

Today, stem cells constitute a research tool which can be used by biologists to study the growth and differentiation of cells basic to our understanding of human development. Discoveries based on their use could lead to treatment of abnormalities in human development and to a source of differentiated cells and tissues for transplantation therapy. With these possibilities of enormous benefit to society, how could one justify banning the use of federal funds for such research, especially since this type of work does not impinge directly on the morality issues associated with cloning of human beings.⁶ Scientists and members of the lay public who support research on human stem cells were pleased by the announcement on January 19, 1999 that "current law permits federal funds to be used for research using human pluripotent stem cells."⁷ That statement by Harold Varmus, as Director of NIH, was based on an interpretation of existing law by the general counsel of the Depart-

ment of Health and Human Services. Based on that interpretation of existing rules and clauses in appropriation bills, which differentiated between the development and use of stem cell lines, the NIH published thoughtful and carefully crafted guidelines in the *Federal Register* early in December of 1999 for funding research involving human pluripotent stem cells.^{8,9} The comment period for responses to the announcement expired February 22, 2000, and a final statement of requirements for grantees and regulations for acceptable use of stem cells is expected soon. Despite these announced policies, it should be recognized that this contentious issue is not yet settled and that congressional opposition is likely.

The Shelby Amendment, OMB, Circular A-110, and FOIA

It is somewhat ironic that at the time we are contending with government imposed restrictions limiting the freedom of research, we are also being confronted with the possibility of regulations, again from government, that will certainly be very burdensome, expensive, and time-consuming. Moreover this seemingly innocuous action could cause a serious violation of privacy rights, prove deleterious to academic-industrial collaboration, and actually lead to the cessation of potentially promising biomedical research. This issue, arising out of an amendment introduced by Senator Shelby (R-AL) to the FY 1999 Omnibus Spending Bill (Public Law 105-277) of the last Congress, required the Office of Management and Budget (OMB) to revise Circular A-110 so that all data produced through federal funding be made available to the public through procedures established under the Freedom of Information Act (FOIA).¹⁰ Circular A-110 describes the "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations." In response to that amendment in the congressional spending bill, the OMB published some proposed changes in A-110 in the *Federal Register*, and opened discussion of the suggested alterations for public comment.¹¹ The comment period ended on April 5, 1999. In the early part of the 60-day comment period, the number of criticisms and suggestions for modification of the revision proposed by OMB was very limited. Spurred by the American Society for Biochemistry and Molecular Biology and other professional societies, their members communicated detailed criticisms of the proposed Circular A-110. Indeed over 1,000 critical, constructive letters were sent to the OMB before the end of the comment period. But in the last few days before the deadline about 9000 almost

identical messages were sent to the OMB by members of the NRA and the Chamber of Congress. These messages praised the proposed revisions in Circular A-110. Fortunately, officials in the OMB read the communications, considered the suggestions and criticisms and, in a final revision on September 30, 1999, formulated a reasonable response to an unreasonable mandate.¹² Their revision although reducing the burdens on the scientific community will still permit some potential harassment. It is clear that the use of FOIA is the wrong remedy for the existing problem of making data available. Although Senator Shelby, the author of the amendment to Public Law 105-277, expressed strong criticism of the revised circular, he seemed to accept the OMB formulation and apparently is not challenging OMB's formulation and narrowing of the requirement that "all" data be made available. Others, however, have not given up in the effort to have access to all research data. The United States Chamber of Commerce, in an apparent attempt to provoke a lawsuit over what they termed as OMB decimating Congressional intent, has filed three FOIA requests seeking "key documents, research data and studies that the EPA used or cited in their recent regulations on National Ambient Air Quality Standards, Environmental Justice guidelines, and standards for automobile tailpipe emissions."¹³ We can agree with Senator Shelby in his effort to require that data collected at the Harvard School of Public Health under a federally funded grant and used as part of the justification for proposed EPA air pollution regulations be made available to the public. However, the language of the amendment when applied, for example, to clinical studies funded by NIH would virtually cripple such investigations because of the violation of the privacy of patients. Similarly, the violation of proprietary information in academic-industrial collaborations through supplying the data, required by the Shelby amendment, would have a chilling effect on the way that collaborative science is conducted.

Although many of us applaud the purposes of the Freedom of Information Act, and FOIA has been used for good purposes in our society, it behooves us to be aware of the unintended consequences that may result from its implementation. Some groups, displeased with a government regulation or the conclusion of a scientist regarding the efficacy of a drug used in a clinical trial, use FOIA for harassment. Imagine an investigator and a university receiving the following note from a manufacturer who used freedom-of-information provisions to request

...all records relating to study design and methodology, study protocol(s), individual data for all study results and data, data sets, statistical calculations, methodologies, and analyses; correspondence, meeting minutes, notes and other documentation of Dr. X and any other University researchers, any departmental staff or other research committees; meeting minutes, reports and other documentation by Institutional Review Board and/or any other oversight committees within or outside the University.¹⁴

In a letter dealing with the original OMB response to the Shelby Amendment, Bruce Alberts, President of the National Academy of Sciences, wrote:

The potential implications of applying FOIA to federally funded research are daunting. For example, in a famous FOIA lawsuit from the 1970s involving a large, NIH-funded, long-term clinical study by private federally funded research grantees, the plaintiffs were seeking access rights under FOIA to more than 55 million grantee records! The U.S. Supreme Court ultimately ruled against the plaintiffs in that case; this is why, until the recent action by Congress, other federal research grantees have not faced this type of problem.¹⁵

We obviously do not know how the Chamber of Commerce legal challenges to the OMB revised Circular 110-A will fare. Regardless of that outcome, we share the views of Congressman Rush Holt (D-NJ) that, despite the good job done by the OMB in implementing a bad law, the Shelby Amendment can hinder the open exchange of information and ideas.¹⁶ The long-range solution to this potentially serious curtailment of the freedom to conduct scientific investigations is the repeal of the law. Such a bill was indeed introduced by the late Congressman George Brown, Jr. (D-CA), and Congressman Holt has now assumed the leading role in sponsoring this repeal. We hope that there will be widespread support in this effort. It is worth noting that a proposal requiring scientists to make public their raw data had surfaced in 1997 when a member of the House of Representatives attached an amendment to the spending bill for the Postal Service and the Treasury. The final language in that proposal would have required recipients of federal research grants to submit to the government a plan for making "the results (including all underlying data and supplementary materials)...available for public use and inspection." Fortunately this amendment was voted down.¹⁷

Self-Imposed Secrecy

Let us now turn from beating-up on government and look at ourselves. Many codes of ethics adopted by scientific professional societies and discussions about responsible conduct of science have language dealing with the sharing of research findings or resources. For example, the code of the American Society for Biochemistry and Molecular Biology has the following language:

investigators will report research findings resulting from public funding in a full, open and timely fashion to the scientific community
and

investigators will share unique propagative materials developed through publicly-funded research with other scientists in a timely fashion.¹⁸

How well are we doing in this regard? About a decade ago, many investigators received a letter from a prominent scientist at a non-profit research institution that offered highly desired material on condition

...that recipients (1) not share the material or by-products with anyone else, (2) notify the providing institution 60 days in advance of any publication, and (3) yield the providers first rights on any improvement of the vector or products made with it.¹⁹

Although many scientists signed this unconscionable agreement, others were outraged and vociferous in denouncing the “offer,” and some institutions, through their technology licensing offices, objected to the conditions. What is the government policy relating to the distribution of unique resources produced with Public Health Service (PHS) funding? According to the policy statement, unique resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Now let us look at the policy of the PHS relating to the distribution of unique resources produced with PHS funding:

It is the policy of PHS to make available to the public the results and accomplishments of the activities that it funds. Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the deliv-

ery of medical care. Therefore, when these resources are developed with PHS funds and the associated research findings have been published or after they have been provided to the agencies under contract, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. This policy applies to grants, cooperative agreements, and contracts.²⁰

This policy seems clear, and one wonders how well it is being implemented and whether grantees adhere to it. Investigators conducting biomedical research frequently develop unique resources, such as cloned DNA, DNA sequences, and crystallographic coordinates. Let us look at one field of science where there have been numerous complaints and widespread disagreements over the issue of sharing data.

About 20 years ago, the community of crystallographers was deeply divided over the deposition of atomic coordinates deduced from X-ray diffraction studies. Whereas many agreed that the results of such studies should be made available to biological scientists as part of the publication process, there was a feeling that individual investigators could justify withholding or delaying the deposition of the coordinates in data banks customarily used by the scientific community. This justification was based on the need of the crystallographer for continued refinement of the structure and the recognition that the years of effort required to determine a precise structure should allow the individuals additional time to exploit their findings. After extensive discussions held by the International Union of Crystallography, where the range of the proposed delay in releasing coordinates varied from four years to zero years, a compromise was generally accepted where the maximum hold period would be one year. In the following decade it has become increasingly common for coordinates to be deposited in the Protein Data Bank (PDB) with no hold at all, but the one-year option was frequently used. Because the PDB does not release coordinates without the express authorization of the depositors, there was no assurance that such coordinates will be released in a timely manner. In addition, some investigators do not deposit the coordinates, despite publishing detailed papers containing structures.

As in other branches of science, the field of crystallography has changed dramatically. There are many more laboratories throughout the world doing crystallography, the techniques have improved enormously, the average time required to determine a structure has been re-

duced a great deal, and biological scientists require and use the results of X-ray diffraction studies at an ever increasing pace. It was, therefore, the view of many scientists that coordinates should be deposited in the PDB and be made available to biological scientists at the time the paper is published.²¹

In the view of researchers in very diverse fields, the essential characteristic of a scientific publication is that the results be accessible both for validation of the work and for its extension in new directions. Hence, they maintain that all the necessary information must be made available at the time of publication. If individual crystallographers, academic or industrial, wish to satisfy special concerns by withholding data then they should delay the publication of the work in the scientific journals until such time as all information can be made available.

Stimulated by complaints over delays in obtaining access to important results in published papers, a group of distinguished crystallographers wrote to Dr. Harold Varmus, Director of NIH, in early 1998, expressing the view that coordinates from crystallographic studies be released at the time of publication. Through his intervention, that position was then communicated to the Editors of about ten major scientific journals in which structures of macromolecules are frequently published. As a result of the ensuing discussion, the policies of many of the journals were altered in 1999 so as to require that detailed structural information be made available at the time of publication.^{22, 23} It is astonishing that a significant number of reputable journals still do not require as a condition of publication that the relevant evidence be available when the paper is published. In the interim, revisions were announced in NIH policies relating to deposition of atomic coordinates into structural databases.²⁴ Now purse strings can be used to implement policies requiring sharing of data obtained with federal funds.

Institutionally-Imposed Secrecy

In my use of the phrase “self-imposed,” I refer not only to scientists who withhold data but also to institutions which impose limitations on the dissemination of the results of scientific investigations. In the past few years, there have been several egregious examples of the attempted suppression of research findings that deserve the attention of the scientific community. In response to a major struggle²⁵⁻²⁷ involving Dr. David

G. Kern as director of the Brown University Program in Occupational Medicine, the American Thoracic Society released the following:

Barriers to the open communication of scientific information must be resisted. In particular, the threat of litigation and/or elimination of financial support to prevent the open communication of scientific information is abhorrent.²⁵

Beginning with a visit of a textile worker referred to him by a pulmonary physician, Dr. Kern at the Memorial Hospital of Rhode Island Occupational and Environmental Health Service became deeply involved in a conflict encompassing scientific integrity, ethical issues in the practice of occupational medicine, and the release of information essential to the health of patients. This initial visit led to the discovery by Dr. Kern, as the director of the Brown University Program in Occupational Medicine, of a cluster of cases of interstitial lung disease among employees of a textile manufacturing plant. According to Kern's account, he and his team met increasing resistance in their efforts to uncover evidence of a work-related cause of the disease and to communicate their findings to the workers and the union. As in most struggles, there are different points of view, and this case is no exception. The company, with some officials of the medical school and the university supporting them, maintains that an Agreement of Secrecy and Confidentiality precluded dissemination of the findings. That Agreement dealt with trade secrets, and one would be hard pressed to conclude that the confidentiality agreement could be construed as preventing the reporting of potential risks to the health of employees. The problems escalated when the plant's management dismissed the occupational medicine team and threatened legal action if it published or presented its scientific findings. Neither the administration of the Medical School or that of Brown University seemed willing to come to Kern's aid in this struggle. This posture is particularly ironic since the Operating Principles and Guidelines of the hospital and university for the program in occupational medicine lists as its second point:

It is accepted that our primary objective as occupational health consultants is to promote and protect the health and safety of employees.²⁵

It is hard to conceive of a confidentiality agreement not being superseded by medical school officials when patient risks are involved. The

issue was stated clearly by the American College of Occupational and Environmental Medicine.

History is replete with examples where delay or suppression in the reporting and dissemination of health risks led to serious human and financial consequences.²⁵

The issues raised by the Kern case are evident as well in the conflict involving Dr. Nancy Olivieri, the Hospital for Sick Children, and the University of Toronto. That two-year struggle²⁸⁻³¹ dealt with informing patients of the potentially harmful effects of a drug being used in treatment of them, the publication of results of clinical trials, and the enforcement of a confidentiality agreement she had signed with a company financing the clinical trials she was supervising. During the trial, Dr. Olivieri discovered that the drug being used to treat patients suffering from thalassemia was actually causing toxic effects rather than benefiting them as originally thought. Despite threats from the company funding the clinical trial, she did publish her results and conclusions, leading to her dismissal as the principal investigator in the study and as director of the hemoglobinopathy program at the Hospital for Sick Children. The furor over this case received widespread publicity throughout Canada and attracted the attention of leading hematologists in the United States and England. Through their intervention, this unfortunate matter has been resolved, validating the actions of Dr. Olivieri in releasing information to patients that a treatment may be deleterious (rather than beneficial).³¹ It is difficult to understand how the officials in the drug company and the hospital failed to recognize that informing patients of potential harm from a treatment and communicating such information to the medical community at large must take precedence over any confidentiality agreement. This case provoked John Polanyi, a University of Toronto Nobel Laureate, to remark, "Even in an age of commerce, we need enclaves in our society where the views that are expressed have not been purchased."²⁸

Academia and Industry

Suppose your university or research institute was seeking industrial support for some of its research activities. Can you imagine an agree-

ment containing the following clause?³²

Company X would provide Institution Y “general funding” for research of its choice in return for an exclusive worldwide license to all Institution Y inventions related to medical or manufacturing products, excluding existing research agreements with third parties.

Indeed, such a proposal was made and it included the following:

Company X would be allowed to review invention disclosures stemming from federally funded research at Institution Y before the disclosures are filed with the government.

Although Institution Y seemed willing to accept this proposal, the outcry over this proposed agreement reached Congress and led to its demise, but the issue of “reach through” rights imposed or suggested by many companies has become too common.

I illustrate this issue by a report³³ of the discussion at a meeting a decade ago where

The Chief Executive Officer of Corporation X shocked a roomful of investors, analysts and even his own scientific board members when he told the group he’d come up with a plan to commercialize the then brand-new technology known as ZZZ. In a crowded conference room, the CEO explained how he planned to offer non-exclusive licenses to all academic researchers as well as anyone else who bought automated ZZZ systems and they could amplify Y to their heart’s content in any research lab. But if a product eventually results from this work, he told the room, Corporation X would expect royalties on it.

Many in the room were floored. The company’s own scientific advisors engaged the CEO in a heated argument. One suggested it was akin to demanding royalties from a best seller when all you did was sell the author a typewriter. While the ZZZ technology’s use in test kits and for specific diagnostics has become a viable, protected business, the idea of following its trail to a marketed product never worked.

The issue of reach-through rights and the implementation of patents

by commercial concerns is illustrated by the following letter received by an academic scientist:

The animal(s) contained within this shipment are produced and distributed under patent rights licensed from Company X. The recipient of the animal(s) is NOT authorized to breed, cross-breed, reproduce, transfer possession of, or otherwise make ANY use (including use for research purposes) of the animal(s) or biological material derived therefrom (including without limitation cells, eggs, or embryos), without first obtaining a license from Company X. Any making, using, offering to sell, or selling of the animal(s) or any biological material derived therefrom without an appropriate license will be considered an infringement of the patent rights by Company X.³⁴

According to a recent news brief in *Science* entitled, “NIH, DuPont Declare Truce in Mouse War,” the license agreement sent to investigators limited their freedom to use and share the Cre-lox animal.³⁵

DuPont asked that anyone using Cre-lox methods send the company prepublication copies of their scientific reports. The company also tried to acquire commercial rights to future inventions that might arise from experiments involving a Cre-lox animal. In addition, DuPont’s lawyers warned researchers not to share Cre-lox mice with colleagues unless the recipient agreed in advance to DuPont’s terms.

Fortunately, that company position of reach-through rights has now been abandoned for academic researchers. In commenting on a landmark agreement between DuPont Pharmaceuticals Company and the Public Health Service, Paul Friedman, the President of the company, emphasized the company’s commitment to the “wide dissemination of this valuable technology to the academic community”.³⁶ Dr. Maria Freire, Director of NIH’s Office of Technology Transfer, who was involved in this important negotiation summarized the position of NIH with the comment, “We hope that the agreement will serve as a prototype for how a commercial organization can put a technology into the academic domain.”³⁶

Bayh-Dole Act

How did all this happen? Why do you need a license to obtain a reagent from a colleague at another university? Has the culture of credit among scientists changed? Should investigators think about patenting their discovery or invention rather than publishing it in a scientific journal? Have you contacted your Technology Transfer Office? Have you signed the Material Transfer Agreement? These and many analogous questions are raised as a consequence of the major changes resulting from passage of the Bayh-Dole Act about 20 years ago.³⁷

For many years, government-sponsored research, especially through NIH and NSF grants, led to an outpouring of exciting scientific results which were all in the public domain. There appeared to be little incentive for commercial development of the new technologies. As a consequence according to the metaphor in the seminal article by Garrett Hardin, entitled "The Tragedy of the Commons," the great discoveries were available to all, but no one benefited.³⁸ Hence Congress began encouraging research institutions to patent discoveries arising from federally-funded research and to transfer the technology to the private sector. This action by Congress in 1980 took the form of the Bayh-Dole Act and the Stevenson-Wydler Innovation Act. Their purpose was to promote the economic development of the products of federally funded research, thereby benefiting the public through commercialization of advances in research and technology. In effect, these acts provided incentives for private parties to develop useful products from research results that might otherwise not have been exploited. Through these laws, recipients of government funding can elect to retain title to their inventions, but the laws impose the obligations to promote utilization, to encourage commercialization and to encourage public availability of the products.

By and large, the Bayh-Dole Act has been remarkably effective, especially in the area of biotechnology, an industry which originated from the science of NIH-funded research. But it appears now that we have gone to the other extreme. Privatization, though helping in overcoming the Tragedy of the Commons, could lead, according to Heller and Eisenberg, to another tragedy—"The Anticommons in Biomedical Research".³⁹

As Eisenberg has pointed out, these statutes (the Bayh-Dole Act and the Stevenson-Wydler Act) encourage research institutions to patent discoveries made through government-sponsored research.⁴⁰ This turning to patents rather than simply publishing results constituted a major

change in policy for scientists and non-profit research institutions. Thirty years ago, most scientists thought that the best way to obtain utilization of the results of publicly-sponsored research was to make them freely available through publications in scientific journals. Now it is recognized that if published research results are available to anyone who wants them, they may not attract sufficient commercial interest to warrant development into useful products. As a consequence, institutions performing federally funded research are increasingly obtaining patents and offering licenses to private companies. Experience over the last 20 years has demonstrated that this change in culture, from publications to patents and licenses, has been accompanied by significant impediments to the ongoing research in universities and other non-profit institutions.

Intellectual Property

A by-product of the Bayh-Dole Act and the increasing use of patents and licenses by universities has been the focus on intellectual property rights and interests of the public and private sectors. The contrasting views over intellectual property was summarized in the Introduction to the Summary of a Workshop on Intellectual Property Rights and Research Tools in Molecular Biology, as follows:

University scientists complain that the eagerness of private firms to preserve intellectual property poses a threat to open scientific communication, that the prospect of obtaining patents influences research agendas, that overly broad patents stifle research, and that licensing practices impede access to and use of genetic materials and DNA technology. Yet few scientists today would voice wholesale opposition to patenting itself; scientists' concern is more likely to be how to ensure access to patented inventions on reasonable terms. Representatives of the private sector have a different list of complaints, including the overeagerness of university technology transfer managers to file patent applications, their overestimation of the value of their intellectual property, the underestimation of the additional investment required to turn a research discovery into a product, and their readiness to grant exclusive, rather than non-exclusive, licenses.⁴¹

Regrettably, increasing commercialization of research results has blurred the distinction between "research tools" and "products." As a

consequence, we have witnessed the patenting and licensing of basic research tools, such as PCR and Cre-lox, which historically were exchanged freely and directly among scientists without licenses, material transfer agreements or memoranda of understanding. Whereas investigators used to devote little thought to a financial return when their lab was involved in constructing a plasmid or a mutant protein, now the perspective is different.

Research Tools

As a result of complaints from scientists involved in biomedical research, a working group was established by the Director of NIH in order to devise remedies for the increasing difficulties and delays in gaining access to research tools. In their report on June 4, 1998, the group enumerated the more significant problems and their recommendations for resolving them.⁴² They also pointed out the sometimes conflicting goals and obligations of NIH. On the one hand, NIH has a strong interest in facilitating the use of research tools in both the public and private sectors. At the same time, NIH is required to promote commercial development and widespread availability of discoveries derived from NIH-funded research. The working group noted that “case by case negotiations for permission to use research tools and materials create significant administrative burdens that delay research.” The members of the working group, in their discussion of problems, stated that:

Institutions that seek to retain a competitive advantage from their proprietary research tools are generally unwilling to make them freely available. In order to minimize risks of competitive harm they may seek to limit who has access to the tools, restrict how they are used, and restrict or delay disclosure of research results.

The final and very important problem cited by the group was:

License mechanisms by which tool providers seek to profit from the future discoveries of tool users often involve future royalty obligations or rights to future intellectual property.

In proposing remedies, the working group made a series of recommendations:

- NIH should promote free dissemination of research tools without legal agreements whenever possible, especially when the prospect of commercial gain is remote.

- NIH should promote use of the Uniform Biological Materials Transfer Agreement (UBMTA) and the development of other standard agreements to reduce the need for case-by-case review and negotiations.
- NIH should develop and disseminate guidelines for recipients of NIH funds as to reasonable terms in licenses and MTA's, addressing both importing of research tools from other institutions and exporting of research tools created with NIH funds.

In response to this report of the working group, NIH published a notice in the *Federal Register* on May 25, 1999, describing a proposed policy for sharing biomedical research resources, and the final notice, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Research Resources," appeared on December 23, 1999.⁴³ It is difficult to believe that there could be opposition to the stated principles: Ensure Academic Freedom and Publication; Ensure Appropriate Implementation of the Bayh-Dole Act; Minimize Administrative Impediments to Academic Research.; and Ensure Dissemination of Research Resources Developed with NIH Funds. But it is in the Guidelines for Implementation that we can expect vigorous protests such as the comment of a biotech executive who termed the action "an unmitigated disaster" and called it "Varmus's revenge".⁴⁴ Just as those from the industrial marketplace and from technology transfer offices of major research universities will oppose the NIH rules (or damn them with faint praise such as "a good step"), the scientists in academia will complain that the guidelines do not go far enough toward achieving the tool sharing principles. Clearly the "devil is in the details." Reconciling the mandate of the Public Health Service policies and that of the Bayh-Dole Act will continue to pose problems that are not resolved by the new NIH guidelines. Many research scientists in academia recognize the increasingly onerous barriers to free and open exchange of scientific information and materials resulting from the creation of material transfer agreements and establishment of technology transfer offices on university campuses. They yearn for the return to the era where collegiality and sharing took precedence over commercial considerations.

Summary

It is clear that impediments to the free exchange of materials, ideas, and results are attributable in part to each of the constituencies involved in the research enterprise. At the one extreme, some scientists increasingly are not sharing the products of their research. They are aided and abetted in this withholding by the universities in which they work. The widespread installation of technology transfer offices with the hoped for goal of developing revenues is contributing to the barriers which defy the openness essential in institutions responsible for creating and dispensing knowledge. As a result of their interactions with industry, both the scientists and the universities are responsible for imposing additional curbs leading to the new secrecy. The merging of academia and industry is bound to introduce serious problems since their goals and functions are so disparate. Finally, the interplay of diverse political forces leads to government policies which are frequently in conflict with one another. Some policies lead to seemingly unnecessary burdens on scientists thereby interfering with research activity. More importantly, other actions of government prevent important types of federally funded biomedical research which could be of enormous value to our citizenry. A resolution of the contrasting goals of the Public Health Service calling for sharing and those of the Bayh-Dole Act which lead to privatization is sorely needed. Also a reappraisal of our patent policy regarding organisms and genes is essential, so that patenting of materials with unknown functions like expressed sequence tags (EST) is not permissible. In considering the culture change in our research institutions, one is reminded of the comment of H.L. Mencken:

“If they say it’s not about money, it’s about money.”

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