For Your Information
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RECEIVED MAY 2 3 1979

To market, to market . . .

New Patent Policy Bill Gathers Congressional Support

Like many other researchers, George Tsao found out that the headaches begin at the moment one's results become a "discovery." Tsao and his colleagues at Purdue University discovered a technique in 1975 for converting biomass to usable energy. Purdue administrators attempted to patent the so-called "Tsao process" in order to grant licenses to R&D companies interested in bringing the process to market. But there was a catch: The work had been supported in part by an NSF grant and a Department of Energy contract, and the federal government doesn't like to turn over patent rights on inventions discovered with public funds.

Tsao was luckier than most researchers. His plight was brought to the attention of Sen. Birch Bayh (D-Ind.), whose office spent a year pressuring DOE to agree to release its patent rights, or "title," to Purdue. It wasn't until the Tsao process captured the public fancy through an article in *Popular Science*, and the researchers received a $2 million contract from the Indiana state legislature for further development, that DOE relented.

"I guess our story has a happy ending," Tsao said in a recent telephone interview. "But there were a lot of headaches and frustrations along the way. And there are a lot of stories that do not turn out as happily as ours has."

Capitol Hill is buzzing this spring with politicians trying to see to it that other stories do turn out as happily as George Tsao's. Birch Bayh, chairman of the Senate Judiciary Committee's Subcommittee on the Constitution, is coauthor, with Sen. Robert Dole (R-Kans.), of a bill that most observers feel is a good bet on passing Congress this session. The bipartisan bill has attracted 23 cosponsors, ranging in political coloration from Sen. George McGovern (D-S.Dak.) to Sen. Strom Thurmond (R-S.C.), and more congressmen are signing on every week. The bill has something for everyone and is carefully constructed to avoid offending anyone. It has the enthusiastic support of university patent administrators and scientists, as well as representatives of the small business groups it also would protect.

Hearings on the "University and Small Business Patent Procedures Act" (S. 414) are scheduled into June, and witnesses have been well primed for the event. The issues are not new, and the refrain has been sounded often: With more than 20 different patent policies, varying from one government agency to another, the university-based scientist is at a loss to know what to do with a discovery once it is marketable. If the work has been done on a government grant or contract, and the government insists on retaining title to the invention, the odds are the discovery will never see the light of day.

Of the 27,000 to 30,000 inventions now in the government's patent portfolio, an estimated 4% have been licensed, and far fewer ever make it to the commercial marketplace. Universities are better at licensing the patents they retain—patents granted by the funding agency through an ad hoc waiver or, in the case of some HEW and NSF grantees, a blanket Institutional Patent Agreement (IPA). At some institutions, the licensing rate of university-held patents approaches two-thirds.

Critics of government patent policy say Uncle Sam has been a dismal failure at delivering public inventions to the public. One reason, they say, is that he insists on issuing "nonexclusive" licenses. According to this arrangement, any number of companies may jump in at any point along the costly road to market to claim a piece of the invention as their own. Few corporations, especially small businesses, are willing or able to invest heavily in development of an invention—estimated to cost as much as 10 times the cost of the original invention—if there is no guarantee that their marketable product will be protected from exploitation by competitors. Under the IPA arrangement now in place at 72 NIH grantee institutions and about 20 institutions on NSF grants, universities are required to make good-faith efforts to find takers for nonexclusive licenses. But in practice virtually all licenses let by universities are, with certain restrictions, exclusive.

Another reason the government fares so poorly in licensing its patents, say scientists, is that it doesn't quite know what to do with them. The further one gets from the heart of a discovery—the inventor—the less one knows about how best to promote and shepherd its development.

Because it transfers patent rights back to the university, the IPA arrangement is the one most favored by campus research managers. The Association of American Universities, American Council on Education, and Society of University Patent Administrators appear each year, like the cherry blossoms, to rally behind the IPA whenever it comes under congressional fire (see September 1978 *BioScience*, p. 605). This year, however, the sentiment on Capitol Hill has shifted, and the traditional AAU, ACE, and SUPA witnesses are more at ease. Their pet, the popular Dole-Bayh bill, not only would preserve the IPA, but would expand it.

IPA and the Dole-Bayh Bill

The IPA presently is limited to only a few nonprofit institutions and is applicable only to inventions discovered on government grants, not contracts. But S.414 would make the agreement applicable to all grantees and contractors, for all universities and small businesses conducting research supported by all sectors of government. The only exclusion in the bill is big business, a tactical exclusion taken to assure the bill's liberal support. "The big guys can afford to support their own research," says a Bayh aide, who hastens to add that large corporations will, as before, be subject to case-by-case review of agency waivers of patent rights.

The Dole-Bayh bill would allow contractors and grantees even more flexibility than does the current IPA program. As now administered by HEW, a university must have "proven technology-transfer capability" to qualify for an IPA. "We dropped that requirement," explains Bayh's aide. "We just decided that the contractor in almost all cases is more able to transfer the technology than is the agency. The universities have a much better track record at licensing than the government, and that's partly because the inventor has a much better idea of how to market the invention than does some bureaucrat in Washington."

Another IPA restriction dropped in the Dole-Bayh bill is the requirement that grantees and contractors try first to offer nonexclusive licenses. "It's too long and inefficient a process," the aide says. "Universities don't have the financial capability to beat the bushes and try to find someone who is willing to accept a license on a nonexclusive basis." Besides, he adds, if the invention turns out to be a moneymaker, some company could always bring the university to court to protest that it would have accepted a nonexclusive license if it had been offered. Such a contention is difficult to disprove, and the university, under current IPA requirements, could be liable.

Ironically, the Dole-Bayh bill institutionalizes the IPA at the same time the IPA is in danger at the agency where it all began in 1968—HEW. According to a still-unreleased General Accounting Office study of government patent policy, conducted at the request of Bayh's subcommittee, HEW has been moving recently toward reneging on its IPAs. In a draft summary of the GAO report obtained by *BioScience*, the investigative office notes with some alarm that HEW may be headed back to square one in its patent practices. The summary invokes an earlier GAO study, conducted in 1968, which found that HEW was "blocking development" of pharmaceutical inventions and "impeding cooperative efforts between universities and the commercial sector" by retaining title to inventions discovered with departmental support. That report led to the introduction of the IPA program at HEW in 1968, and its expansion to NSF in 1973. But the HEW mood in the last few years, GAO says now, has been less than enthusiastic about IPAs.

Right Place, Right Time

Science policy observers tend to agree that the Dole-Bayh bill has a better chance of passage this year than did any of its many predecessors. One reason is that the tenor of the debate has shifted recently. No longer is the issue of government title versus university title cast as a liberal vs. conservative issue, with liberals insisting that all inventions discovered with public funds belong in the public domain, and conservatives stating that the free enterprise system is the only way to get new inventions to the marketplace. The issue today is presented more as a component of a new catchword in bureaucratic circles: innovation.

President Carter has requested a high-level domestic policy review on industrial innovation, and he expects to receive at least part of the report and recommendations, originally due 1 April, some time in mid-May. One component of that review, coordinated by the Commerce Department's science director, Jordan Baruch, is a look at government patent policy. The subcommittee set up to draft recommendations regarding patents, which is chaired by attorney Robert Benson of Allis-Chalmers in Milwaukee, supports the theory behind the Dole-Bayh bill. "In the case of university or private contractor work supported by the government," wrote the Benson group in its December 1978 draft report, "the members of this subcommittee recommend that title to the patents should go to the university or private contractor. But some members feel the government should have 'march-in rights' [allowing for transfer of patent rights if the agency feels the discovery is moving too slowly]. In all cases, the government would retain a nonexclusive license to use and have made for its use inventions funded in whole or in part by governmental expense." A vote of confidence from the Benson subcommittee, whose clout is yet to be tested, can probably only help the Dole-Bayh bill, which contains the very same safeguards—march-in rights and nonexclusive licensing to the government.

In its effort to be all things to all people, the Dole-Bayh bill contains another provision aimed at muting critics of previous attempts to institutionalize the IPA: a payback clause. Consumer advocates such as Ralph Nader have in the past vigorously protested transfer of patent rights to grantees and contractors, stating that if the invention becomes a big profitmaker, the government will lose out on a potential windfall. The payback provision in S. 414, however, asserts that if a small business makes a sizable profit on its government-funded invention, it must split the royalties until it has reimbursed the government for the amount of the original grant.

"They had to put that clause in to make the bill politically salable," says an aide to Sen. Adlai Stevenson (D-Ill.), who is rumored to be considering drafting an innovation bill that touches on patent policy. "But I shudder to think of the administrative hassle that would be entailed in trying to determine exactly what the government's contribution was to the invention."

"The idea that what the government pays for belongs to the people is not only appealing, it is true," wrote the Benson subcommittee on patents and industrial innovation. "The question is: What instrumentalities can be brought to bear to maximize the possibilities that the people will indeed have available the fruits of their government's expenditures?" Nonexclusive licenses to

Senators Press Press

With friends like the Senate Science, Technology, and Space subcommittee, Frank Press doesn't need enemies. The President's top science adviser was treated to two-and-one-half hours of questioning on 21 March by two of science's staunchest congressional supporters, subcommittee chairman Adlai Stevenson (D-Ill.) and ranking minority member Harrison Schmitt (R-N.M.). The queries came so fast and furious that Schmitt felt compelled to reassure Press, as the hearings ended, that the senators still loved him. "We will continue to have discussions and minor disagreements," Schmitt said, "but we appreciate everything you're doing."

Some of the questions, though, were less than appreciative. Schmitt wanted to know whether the so-called basic research push in the FY 1980 President's budget was in fact a real growth or just a shell game. Stevenson wanted to know why Press' Office of Science and Technology Policy (OSTP) hadn't managed to institutionalize its advisory functions to assure its own usefulness beyond Press' tenure. Schmitt wanted to know why the administration was not placing greater emphasis on efforts in earthquake hazard mitigation, particularly in developing techniques of earthquake prediction. Stevenson wanted to know why the government seemed incapable of distinguishing effectively between contract procurement and grant management.

The most salient question of the morning concerned OSTP's delegation of the very functions that Congress had considered most important when it wrote the National Science and Technology Policy Act of 1976. "The Science and Technology Committee has been abolished," Stevenson said, recounting OSTP's shortcomings. "The two-year survey on science and technology activities wasn't done. The annual report requirement has been transferred to NSF, and the five-year outlook transferred to NSF and the National Academy of Sciences. These were all, rightly or wrongly, attempts to

Frank Press

institutionalize this function in the government in a systematic, ongoing way."

Press defended his agency's decision to ignore part of its mandate by citing chapter and verse from another agency's mandate. He said President Carter shifted responsibility for the two reports to NSF (December 1978 *BioScience*, p. 753) to give the foundation and the National Science Board something important to do. NSF, Press said, is mandated by law to act as "a source of major policy advice in science and technology to the country," and the annual science and technology report and biennial five-year forecast seemed good ways to do so. The presidential adviser added that Congress had been informed of the decision long before the transfer was implemented. When asked whether he was satisfied with the job NSF had done on its first annual S&T report, sent to Congress last fall eight months after its deadline, Press said he was not.

Stevenson was sharply critical of the administration's effort, in the FY 1980 budget, to cut back on USDA's four regional labs, one of which is located in his home state. The government laboratories—in Peoria, Illinois; Philadelphia, Pennsylvania; New Orleans, Louisiana; and Albany, California—have received significant budget cuts in the administration's renewed push to increase the USDA competitive grants program. Stevenson said this effort to conduct more and more agricultural research at extramural labs, most of which are located at land-grant colleges and universities, could mean a shift from truly public-oriented research to research geared to meet the needs of the agricultural industry.

"The research in agriculture conducted in the land-grant colleges has, over the years, given us a highly productive agriculture," the senator said, "but it's given us a highly capital-intensive agriculture which benefits the manufacturers of the equipment and agricultural chemicals, who in turn support land-grant college research." USDA labs, on the other hand, are not beholden to the agricultural industry, he said. "They are beholden to the farmers. They have an interest in decreasing the cost of the inputs of production of food and will, for example, help develop encapsulated fertilizers to make them more efficient to decrease the consumption of fertilizers. The manufacturers of fertilizers have a diametrically opposed interest and incentive." Because the survival of land-grant colleges is intimately bound to the health of the argichemical industry, Stevenson said, researchers working at these institutions "can be influenced, at least subconsciously, by other benefactors of such research, including equipment and chemical processors or producers," rather than the interests of farmers and consumers.

Press agreed that government labs should not be closed willy-nilly, but he differed on Stevenson's point that they better serve the public interest and thus deserve special protection in a time of scarce resources. If USDA labs cannot measure up to private labs, he said, they should be screened through peer review and made to face the consequences. "I would remind you," Press added, "that there is legislation that originated in Congress that forces the government whenever possible to move its expenditures out of government and into industry and the private sector." —R.M.H.

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undeveloped inventions are not the answer, the subcommittee reasoned; "patent ownership or exclusive licenses of sufficient duration are much more likely to attract the money and talent needed to make and market real products to meet consumer needs."

Patenting Life Forms

The subcommittee also urged "further study" of the applicability of patents to particular cases emerging from a new field of biological research: recombinant DNA technology. This recommendation took on an added urgency three months after the draft report was issued, when the U.S. Court of Custom and Patent Appeals ruled, for the second time, that new life forms can be patented. That decision is certain to have a profound effect on the future of recombinant DNA re-

search at both universities and private corporations, say government officials, and may change the shape of medical practice, especially in pharmaceuticals, over the next several years.

The court's recent ruling was a reiteration of a 1977 decision, which had been appealed to the Supreme Court. Two separate instances were involved: one, a patent application for a new kind of bacterium, purified by scientists at Upjohn, that is capable of producing the antibiotic lincomycin; the other, an application to patent another bacterium, created through recombinant DNA technology in the labs of General Electric, that degrades oil spills. The appeals court had ruled, in a 3-2 decision, that the new life forms were patentable. The Commerce Department's Patent and Trademark Office appealed, citing the patent law's enumeration only of a new "process, machine, manufacture, or composition of matter" as within its purview.

Last summer, the Supreme Court ruled on another case involving the patentability of computer software (since it constitutes merely the discovery of a "law of nature," the high court ruled, it cannot be patented), and returned the G.E. and Upjohn applications to the appeals court for reconsideration. This time the patent appeals court ruled 4-1 in favor of the corporations. "The fact that microorganisms are alive is a distinction without legal significance," Judge Giles Rich wrote for the majority, pointing out that patents for nonprocess inventions involving life date back to Louis Pasteur's 1837 patent for yeast. Rich said the original patent act need not specify the products of recombinant DNA technology for those products to be patentable, since inventions are, by their very nature, unforeseeable. "From our modest exposure to the realities of the patent system," wrote the court, "we judge the range of subject matter open to patentability to be enormous in any case. It is heartening to think how many useful things may yet be invented and we are not moved to be restrictive in our interpretation . . . by mere number. An appropriate rejoinder, we think, is, 'The more the better.' "

Beyond IPAs

Although the Dole-Bayh bill is receiving nearly unprecedented support, some congressional aides point out that it still leaves unanswered fundamental questions about patents in general and patents on university campuses in particular. That's an issue politicians have been dancing around for years, and they don't seem likely to address it any more directly in this session of Congress.

Patents run headlong into some hallowed academic traditions, especially the publication of research results. When a research finding is published in a professional journal or reported at a scientific meeting, the inventor immediately forsakes all foreign rights to the patent if he or she has not already filed a patent application. Then there are just 12 months in which to file for a patent on the invention in this country. That may seem like a long time, but in the convoluted realm of patent law it is not. University patent administrators thus spend a good deal of their time trying to convince scientists of the importance of cooperation.

"All we ask is that the researchers give us a running start along with them," says Ralph Davis, patent administrator at Purdue. Davis says if scientists make "disclosures" to the university (that is, inform patent administrators of a potentially marketable discovery) in due time—say, as they are submitting their manuscripts for publication—then by the time the patent paperwork is completed the article will just about be in print.

The publication vs. patent application conflict is greater at the federal level than at the university level, said Thomas Jones, research director of MIT, at hearings held last spring by Sen. Gaylord Nelson (D-Wisc.). Nelson is a traditional foe of university retention of patent rights, but he has taken a back seat in the S. 414 debate. According to Jones, universities encourage researchers to publish their results as quickly as possible, and profits be damned. "Universities do not constrain an inventor from publishing the scientific results of his or her research," he said. "Rather, the university relies on early disclosure of inventions, and prompt filing of patent applications, to protect its licensing rights. Compare this with the policy of DOE, which requires submittal of papers 60 days prior to the publication to allow that agency to make decisions on the filing of patent applications, and which gives DOE the right to prohibit publication indefinitely in order to preserve its patent rights."

Another issue still to be addressed is the question of background rights. This question affects small businesses more seriously than universities, since the background information to a particular discovery is often all a small business has to make it competitive in the field. Several agencies, notably DOE, sometimes require a contractor to turn over not only the invention discovered with government funds, but also all previous information the contractor has, from whatever source, that is relevant to the government's ability to license that invention. This arrangement forces many small businesses to shun contact with the federal R&D establishment entirely; some companies even stay away from cooperative arrangements with universities in fear that all their background information will be seized.

Finally, there's the problem of lone inventors, with neither university administrators nor government program officers to guide them through the maze of patent procedure and the costs of patent attorneys. After-hours scientists tinkering in the tradition of Thomas Alva Edison don't stand a chance, it seems, in the competitive world of patents, and some believe the public is losing out on the fruits of some of the nation's most creative minds.

One such inventor, microbiologist David Lewis, works at EPA in Georgia by day and invents termiticides, anti-pollutant mixtures, and waste converters by night. He has abandoned the inventing game, however, after spending more than $4,000 on patent application fees and finding the system "unnecessarily cumbersome, expensive, and inefficient, even to the point of discouraging the development of new technology by private inventors."

Lying fallow on Lewis' shelves are a new termiticide that may be more effective than chlordane, a microbiological process for converting coffeebean waste husks into a usable product, and a steam-activated carbon and mineral mixture that appears effective in removing certain pollutants from water. "No industry will invest in these new developments without patent protection of their development," he sighs. "Therefore, it's useless for me to commit more of my personal resources to develop something that stands little chance of being patented without extensive legal involvement to cope with the language, format, and questionable judgment of patent examiners. Large corporations may easily be able to afford this entanglement, but I can't." The impact of this problem, Lewis says, can be seen by the hard truth that very little new technology on the market today is "the result of private inventors working out of their basement laboratories."

—Robin Marantz Henig