

★ Patent Bill Returns Bright Idea to Inventor

And in the process it would help federally funded inventors and their institutions to pick up a little cash

When your innovative idea gets tied up by piles of paperwork and months of delay as Washington dawdles over whether to let you market the thing or not, nasty thoughts about U.S. patent policy are never far off.

Just ask Sydney E. Salmon, a biomedical researcher at the University of Arizona. In 1977, Salmon and another scientist found that by growing human tumor cells in a Petri dish and adding anticancer drugs, they could predict what drug or combination of drugs would best shrink a patient's tumor. The method could also be used to screen the effectiveness of new anticancer drugs.

Salmon wanted to patent the technique. But since the salary of one researcher in the lab was paid by the Department of Health, Education, and Welfare (HEW), all rights reverted to the agency. To make sure the method did not just sit on a government shelf, Salmon on 5 July 1977 asked HEW for the patent rights, and on 29 July published his results in *Science*. An editorial in the *New England Journal of Medicine* soon took note of the technique, and even *Time* ran a story on it. Not long afterwards, drug companies showed up at Salmon's door, wanting to market the method. HEW, however, had not yet ruled on the patent rights, and the companies soon lost interest. It took until March of this year—in all some 20 months—before HEW finally decided to hand over the rights. The drug companies are only now starting again to ask about licensing the patent rights.

"This invention will spare cancer patients from receiving toxic drugs which we can predict would be of no benefit," Salmon recently told a Senate hearing. "Yet this slow process of gaining HEW approval delayed its availability to the public by at least 1 year."

It is an oft-told tale on Capitol Hill these days. A steady stream of inventors has been showing up at hearings to complain about the bureaucratic knots that tie up the transfer of patents derived from federally funded research. Their goal is to boost new legislation, and it seems to be working. Support has been building for a Senate bill that would automatically give patent rights to universities and small businesses. The bill, the University and Small Businesses Patent

Procedures Act (S.414), is coauthored by Birch Bayh (D-Ind.), chairman of the Senate Judiciary Committee's subcommittee on the Constitution, and Robert Dole (R-Kan.).

The bill would let any federally funded university or small business make some money off their bright ideas. Say, for instance, that a researcher on a Department of Energy (DOE) grant came up with a cost-efficient way of converting coal into gasoline. Under the bill, the inventing organization could apply for a patent—without waiting for permission from DOE—and then license the idea to a company for up to 8 years. A portion of the money made during commercialization would be returned to the inventing organization with the stipulation that the funds, over and above administrative expenses and a fee to the inventor, be used to support further scientific research.

Not only university researchers are backing the bill. A study by the Department of Commerce has recommended the exclusive licensing of patents derived from federally funded research. The General Accounting Office (GAO) has come out in favor of the Bayh-Dole legis-

businessmen. Of the 30,000 inventions now in the government's patent portfolio, an estimated 4 percent have been licensed, and even fewer make it to market. One reason is that the government insists on issuing "nonexclusive" licenses—which means that any number of companies can jump in along the road to development and marketing (though few take the chance). Another reason, say many researchers, is that the government doesn't know how to market an invention. The further one goes from the source of the idea, the inventor, the less one knows about how to put it to work.

The government is not all thumbs, however. To help cut through this web, federal agencies over the years have worked out agreements with certain universities that show a knack for peddling their inventions to companies that will produce them. Called Institutional Patent Agreements (IPA), they allow a university to become the owner of a patented invention resulting from federally funded research and to give an exclusive license to a company for up to 5 years. IPA's are few and far between, however. They are in place at only 72 HEW grantee institutions and, out of 1200 institu-

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tion. And the critics of such legislation, who in the past have railed about the "giveaway of public funds," have grown unusually quiet. The reason seems clear. Industrial innovation has become a buzz word in bureaucratic circles. The White House, for instance, is about to release a study on how to cure the alleged decline in the innovative spirit within U.S. industry. The patent-transfer people have latched onto this issue. It is about time, they say, to cut the red tape that saps the incentive to be inventive.

The way things currently stand, the incentive is indeed small. Years can slip by before a funding agency decides whether or not to return patent rights to an inventor's organization, and, as often as not, the agencies decide to hold on tight. The agencies, moreover, prove to be poor

tions that receive National Science Foundation funds, they are in place at about 20. And not many more are expected, since the agencies are conservative in identifying institutions that have what it takes to promote technology transfer.

The Bayh-Dole bill goes beyond the IPA concept in that it makes no distinction between institutions that have a knack for marketing their inventions and those that do not. It says *any* university or small business can manage its own invention better than the government can. The IPA, moreover, is limited to inventions discovered on government grants, not contracts. Not so with Bayh-Dole. Most everyone on any kind of funding is covered, with the exception of big business, and that is mostly for tactical rea-

sons. "We'd like to extend it to everybody," said one Senate aide, "but if we did, the bill would never have a chance of passing." Such was the situation several years ago when similar patent legislation that applied to all businesses was introduced. Consumer advocates and trustbusters at the time cried giveaway and monopoly, and the bill soon died.

To further mute critics this time around, the Bayh-Dole bill also has a payback clause. This would provide a payment to the federal agency that funded the project, provided the patent proved to be a money-maker. It would give the government 50 percent of all net income above \$250,000 received by a university from licensing an invention—not to exceed, however, the amount of government funding in the first place. It sounds straightforward, but some researchers see problems with it. "In arriving at a remuneration formula, is the government support to be determined on the basis of one year? Two years? Ten years?" asked Baruch S. Blumberg, a Nobel laureate who recently testified on behalf of the bill. "Some grants are now in their 20th year. Resolution of this question could become an accounting nightmare."

Despite such problems, which according to Senate aides will be ironed out in conference, the bill has gained considerable congressional support. It has 28 cosponsors that range the political spectrum from Senator George McGovern (D-S.D.) to Senator Strom Thurmond (R-S.C.). Identical legislation (H.R.2414) has been introduced in the House by Peter Rodino (D-N.J.), chairman of the House Judiciary Committee.

The GAO has also given its seal of approval to the bill. "We believe a clear legislative statement of uniform, government-wide patent policy is long overdue," said Elmer B. Staats, Comptroller General, in testimony before Senator Bayh's subcommittee on the Constitution. He noted, moreover, that a recent GAO study showed that HEW and other departments have been moving from what was once a liberal policy on the transfer of patent rights to one that is much more conservative. He said "an easing of the red tape leading to determinations of rights in inventions would bring about an improvement of this record."

In a move that may gain Administration support for the bill, a Commerce Department study has backed the idea of granting exclusive licenses from federally funded research. The recommendations grew out of an Administration domestic policy review on problems with

industrial innovation. "If the results of federally sponsored R & D do not reach the consumer in the form of tangible benefits, the government has not completed its job and has not been a good steward of the taxpayer's money," said the advisory subcommittee on patents and information chaired by Robert Benson of Alis-Chalmers Corp. "The right to exclude others conferred by a patent or an exclusive license under a patent may be the only incentive great enough to induce the investment needed for development and marketing of products."

Foes of the legislation are few, but they do exist. One is Admiral Hyman Rickover, the Navy's veteran apostle of nuclear-powered ships. The reason so many government-owned patents are not used, he recently told a Senate hearing, is that the vast majority of them are worthless. "These patents are filed defensively, or as status symbols. Other times an inventor simply misjudges the attractiveness of his ideas. . . . In my opinion, the bill overemphasizes the importance of patents, and, if enacted, would divert attention and resources of the government agencies away from their main functions."

Rickover also criticized as cosmetic a provision in the bill for march-in rights (which let the government take back the patent if it feels a discovery is being marketed too slowly). The government has had march-in rights since 1963, he said, but it has never used them. "To be in a position to exercise these rights a government agency would have to stay involved in the plans and actions of its patent holders and check up on them. If a government agency ever decided to exercise its march-in rights and the patent holder contested the action, no doubt the dispute would be litigated for years."

Though Rickover came down hard against the bill, other traditional foes of such legislation have eased up. The Justice Department, usually hostile to anything that smacks of monopoly, says it is reassessing its position. An aide to Senator Russell Long (D-La.), a veteran backer of government-held patents, has told Bayh's staff that the senator will not "actively oppose" the bill. And Senator Gaylord Nelson (D-Wis.), a longtime foe who asked the Administration to suspend new rules for IPA's last year so he could hold hearings to see if they were a "giveaway" of public funds, is not actively opposing the bill, according to his staffers.

With the opposition not putting up their usual fight, is the bill a sure thing? Not quite, say several Senate aides.

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FDA Bans Speed in Diet Pills

The sale of amphetamines, the much-abused stimulants, will be cut back by 80 percent or more if a decision made by the Food and Drug Administration (FDA) on 16 July is made to stick. The FDA announced that, if no valid objections are filed before 16 August, it will ban the use of amphetamines and methamphetamines as an aid to dieting because they have little beneficial effect and pose a significant risk to public health. The FDA decided that the drugs should be given only to patients with a clear need for them—primarily those suffering from narcolepsy (uncontrollable sleepiness) and childhood hyperactivity.

Other countries took this step years ago, and Canada reports that, since it took action in 1971, the volume of amphetamines used for diet control has declined from 757 kilograms a year to 0.710 kilogram. The corresponding figure for the United States is about 2180 kilograms. The FDA has been trying to accomplish a similar ban for nearly 8 years, but unlike the Canadian government, it has become entangled in lengthy negotiations with U.S. amphetamine makers. No companies in Canada make the drug.

John Griffith of the addiction research center at the National Institute on Drug Abuse has reported that "speed" is not much better than a placebo in diet control. This finding is published in the FDA *Federal Register* notice of 17 July. The notice also summarized the findings of Lester Grinspoon, associate professor of psychiatry at Harvard: "After the 3- to 4-week euphoric high, which may cause diminished food intake and consequent weight loss, amphetamines are no longer effective as anorectics unless the user increases the dose, thus initiating a pattern of abuse." The average weight loss during the first weeks is less than 10 pounds, which is of no help to a clinically obese person, particularly since the effect is short-term. If the prescription is canceled after a few weeks—as good medical practice requires—the patient often suffers a "rebound," eating more than before to compensate for the sudden feeling of deprivation.

The effects of long-term use are insidious. According to the FDA report, Griffith found that "dependency often begins with a therapeutic use of the drug, but the use escalates into a chronic repetitive pattern. This... becomes very serious when the chronic use of amphetamines produces insomnia and anxiety, among other symptoms, which give the person the predisposition to use or abuse barbiturates, alcohol, and minor tranquilizers." Dependence of this sort is as difficult to treat as narcotic addiction and has been shown to induce a paranoid psychosis in long-term users.

The FDA has won support for its action from a number of health organizations, including the American College of Physicians, the American Pharmaceutical Association, and numerous state medical societies. But the manufacturers are still resisting. The FDA's rule is open to challenge on technical grounds, and Ronald Wilson of FDA's Bureau of Drugs said, "We are anticipating the filing of voluminous data by Smith Kline & French [SKF]" the maker of 7 out of 30 of the banned diet pills. It may take a year to review the data, Wilson said, and then the FDA will reach its absolutely final decision.

SKF spokesman Jeremy Heynsfeld said it would "come as no surprise to those who have followed the case" that the decision will be appealed. *Science* asked why SKF would wish to market a drug which the FDA had found to be dangerous and ineffective. Heynsfeld read from a prepared text: "Evidence presented to the FDA in 1977 clearly demonstrated that amphetamines are safe and effective for recommended uses and should continue to be available for the short-term treatment of obesity."

The FDA rule, if sustained, will cut back on amphetamines but will not reduce the production or the use of a family of recently invented diet medicines known as "amphetamine-like drugs." These chemical cousins of speed have been designed with slightly altered molecular structures, giving each one unique pharmacological qualities. According to Edward Tocus, chief of FDA's drug abuse staff, these relatives of amphetamines have "similar but different effects on the nervous system" and some potential for abuse. The family includes such brands as Preludin, Ionamin, Tenuate, Voranil, and Pondimin.

Doctors are expected to begin prescribing these in place of amphetamines once the ban takes effect. If these cousins of speed begin appearing in black-market sales, the FDA will consider clamping down on them as well. "There's no way to predict what will happen," Tocus said.

Costs Still Climbing at Three Mile Island

The owner of the Three Mile Island nuclear plant—the General Public Utilities Corporation (GPU)—received two pieces of bad news this summer, one from a contractor and the other from the federal Nuclear Regulatory Commission (NRC). Together they raised questions about the company's fiscal health and darkened the clouds hanging over the nuclear industry.

GPU learned from its contractor, the Bechtel Corporation, that the cost of repairing the crippled reactor on Three Mile Island (unit 2) will be twice or three times what had been anticipated—not \$140 million, but \$240 to \$320 million. This does not include the costs of replacing the reactor core, which GPU believes will be \$60 to \$85 million. Thus the total working estimate is around \$400 million.

Bechtel's report, the first of three, did not conclude flatly that the plant could be rehabilitated. According to GPU, the report said that "so far there has been no evidence uncovered which would indicate the unit cannot be safely decontaminated and restored to service." No one will be certain of the reactor's viability until it has been examined, which cannot be done until the radiation inside the containment building subsides. If all goes well, the reactor might be ready to start up again in 1983.

The utility company learned from the NRC that it will not be allowed to restart the other reactor on Three Mile Island (unit 1) for 18 months or 2 years. This reactor was not damaged in the accident but has been shut down while the NRC considered what it would do next. Joseph Hendrie, chairman of the NRC, angered the utility company in July when he announced that the start-up of unit 1 would be delayed pending a full adjudicatory hearing before an atomic

safety and licensing board (whose members have not yet been named).

Each month unit 1 remains closed, GPU loses \$14 million over and above the losses sustained as a direct result of the accident. GPU hopes to pay for some of the repairs with money from its \$300 million insurance policy, but it will have to find other means of recouping losses not directly tied to the accident. These debts will be amortized and, GPU expects, charged to the ratepayers.

Selling SALT Among the Scientists

The SALT II treaty is not much more popular among scientific societies than it is among senators. As one of the government's SALT sellers, White House science adviser Frank Press has found relatively little enthusiasm among his organized constituency for promoting the treaty.

For example, A. F. Spilhaus, Jr., executive director of the American Geophysical Union (AGU), said: "Press lobbied us to do something on behalf of SALT, but he couldn't give us the information we needed to make an objective judgment." So the AGU refused to do anything. According to Spilhaus, the White House staff was hoping to corral some prestigious support for technical claims made by the treaty's authors. "That kind of pressure was very unfortunate," Spilhaus thought. But he said that officials like Press face an "honest dilemma" in that the data sought by the scientific societies cannot be released without breaching security. Lacking this information, however, the societies are generally reluctant to take a position, for they fear that doing so would be regarded as a political, not a technical, judgment.

Press made one big pitch for SALT last April, when he met with the Council of Scientific Society Presidents. Not much came of that meeting, and none like it have been held since.

The White House staff still hopes that some of the societies will endorse the treaty later in the summer or fall. But at the moment, an Executive staffer said, "With the scientists, we're really focusing on individuals rather than on organizations."

Eliot Marshall

They concede that the biggest hurdle to overcome is the weight of conventional wisdom. It goes something like this. Such a bill would permit the founding of monopolies that can charge high prices for the fruits of tax-aided research. It's a free lunch, say the critics, and it's not fair. One Senate aide who was skeptical of the bill put it this way. "At the stroke of a pen," he said, "you are creating billions of dollars of property that did not exist before, property that is created with taxpayer support. We are not about to jump on the bandwagon. We have an

obligation to the public and to other patent holders. We want to make sure this is good public policy before we start touting its wonders."

For more than 30 years, the government has operated on the assumption that the economic rewards from federally funded R & D should be captured by the government, or shared only grudgingly with others, since public funds were used. Hence, the government's collection of 30,000 patents. That policy, however, has not produced an astounding record of economic returns, and the conventional wisdom on public money

and private gain may be in the midst of change. The innovation "lag," moreover, is becoming pop drama, as evidenced not only by the Administration's domestic policy review but by media coverage such as the 4 June *Newsweek* cover story on innovation, subtitled "Has America lost its edge?" The winds of opinion are shifting. It may no longer take a leap of logic to see that good public policy might include a modicum of private gain, especially when the alternative is patent portfolios that gather dust on government shelves.

—WILLIAM J. BROAD

Whistle Blower Reinstated at HEW

For more than a decade, Norman J. Latker, while working as patent counsel for HEW, urged the department to give the patents derived from HEW-funded research back to the universities that originally did the work. During this time, HEW patent policy became a model for many federal agencies. Then, last December, Latker was bounced out of government service after denouncing an attempt by his superiors to put a lid on patent transfers. He has now, however, been reinstated.

Latker returned to his post as HEW patent counsel at the end of July. The action was called for by a civil service review board that overturned Latker's firing on procedural grounds. HEW, which hedged for 1 month before commenting on the action of the review board, has decided not to appeal the ruling.

The reinstatement is timely. Support is now building for the Bayh-Dole patent bill, and Latker's return to HEW is seen by many university researchers and patent-transfer fans, to whom Latker is something of a hero, as a shot in the arm for their cause.

Latker is anything but a revolutionary. A 22-year veteran of government service, with 15 of them in HEW's patent office, he is credited with helping develop such mild-mannered innovations as Institutional Patent Agreements (IPA), which aid the flow of patent rights from government to universities. The story of their rise at HEW is simple. In 1968, the Government Accounting Office (GAO) investigated the pharmaceutical programs at the National Institutes of Health (NIH) and found no evidence that drugs developed with NIH support ever reached the public. GAO blamed the lack of technology transfer on HEW's practice of retaining all rights to inventions.

After a departmental shake-up in 1969, Latker helped develop a system whereby HEW automatically gave patent rights to the university where a discovery was made and allowed it to license the patent to a private company, which could then develop and market the product. Such IPA's were issued only to universities with a good track record of technology transfer. Latker, however, also urged the transfer of patent rights to universities without such an IPA, eventually releasing 30 to 40 patents a year on such a case-by-case basis. For some time everything sailed along smoothly. Then in August 1977, Latker was ordered to

send all requests for patent waivers up to the HEW general counsel's office. And there they sat. Up until that time, Latker had final say on patent transfers. But no more. The public position of HEW was that all patent matters were "under study," and that no one in the general counsel's office was quite sure just when the review would be finished.

By the fall of 1978, more than 30 requests for individual patents and three requests for IPA's were gathering dust in the general counsel's office. Universities got upset and complained to Congress. So did Latker.

In September 1978, Senator Dole accused HEW of "pulling the plug" on biomedical research. To support the charge, he quoted an internal memorandum from the HEW general counsel's office. "Recent experience with the high cost of proliferating health care technology," it read, "suggests that there may be circumstances in which the Department would wish to restrict or regulate the availability and cost of inventions made with HEW support." HEW Secretary Califano and his advisers had decided to wage war on "runaway medical technology." One way to do so was apparently to deny universities the transfer of patent rights from government-funded research. On 13 September 1978 Dole and Bayh held a press conference and announced a bill that would cut through the backlog. HEW responded quickly. The next day Califano ordered his staff to transfer the patents back to the universities. Within weeks, HEW released 20 of the 30 patents. Soon afterward they also released Latker.

Departmental spokesmen now insist that Latker was not given the boot for blowing the whistle on HEW. Latker was dismissed, they say, because his superior, Richard Beattie said Latker did not meet "professional standards," and because of "specific instances" of misconduct including "forms of lobbying flat out forbidden by the government's codes of conduct."

Latker recently told *Science*, however, that official charges were never brought against him. He was simply fired. But now that the civil service has reinstated him and HEW has decided not to appeal the ruling, Latker says he is simply glad to be back. "It's been a difficult period in my life," he says. "I'm happy to once again have the chance to work with the department." —W.J.B.