

## Assault on the drug jam



NIH

*Anticancer drugs awaiting screening.*

The question of who owns the rights to inventions financed by the Federal Government has been a knotty one.

It has been dormant since midway through the Johnson Administration when revisions in Federal patent policy recommended during the Kennedy years were partially implemented and partially shelved.

**It surfaced again** in Washington last week when, under the combined impetus of renewed interest in the subject by the Nixon Administration and contentions by the drug manufacturers that they represent a special case, about 80 representatives of industry, Government and the universities got together to present their views. The forum was a National Academy of Engineering meeting on the effect of Government patent policy on biomedical engineering.

The meeting left all three groups firmly entrenched in their original opinions: Each institution insists on proprietary rights to drug finds that Government finances, universities make and companies screen and develop.

Except in special contract situations, like cancer chemotherapy and the search for compounds against *falciparum malaria*, drug companies have been refusing to do the initial screening that determines if a university-developed compound has biological activity, unless it gets title to that compound. Specifically, drug companies want long-term exclusivity—sole rights to a compound—and they regard this demand as non-negotiable.

**The main Government** argument to support its taking title, as stated by Manuel B. Hiller, assistant general counsel of the Department of Health, Education and Welfare, is "the inequity of exposing the taxpayer to payment

a second time to procure what his tax dollars have already been spent to produce."

The drug industry contends that the initial research on a compound carried out in a university represents only the first step before it is ready for market.

Says Richard V. Holmes, assistant general counsel for Smith, Kline & French Laboratories, "Basic research is a minor part of the financial effort. The major financial burden is assumed by the company. A man discovers a compound, but it must be screened, tested in animals, tested in man and put in a form acceptable to the Food and Drug Administration. This requires intensive investment."

Holmes estimates that it costs a drug company from \$2.5 million to \$4.5 million just to bring a single drug out and may take five to seven years.

Although the Government does grant some exclusivity, it is limited to three years after a drug is first sold; the companies want at least seven.

**But now enter** a third party to the argument: the university. As a title-holding middleman, it was brought in by the Government so that developmental licenses could be awarded to drug companies; because of a 1924 legal decision, the Department of Health, Education and Welfare has felt that it could not relinquish title to anything it owns except where specifically authorized. To overcome this problem, HEW has had a policy of not taking title to a compound but permitting universities to do so.

That position cracked this week, when the department announced that its agencies could grant limited exclusive licenses to drug companies and others in particular cases where the Government feels the public interest would be served.

### OCEANOGRAPHY

## A chance for NOAA

"Sec. 103. (a) There is established, as an independent agency within the executive branch of the Government, the National Oceanic and Atmospheric Agency . . ."

H.R. 13247 would seem to be a constructive enough bill, creating a new organization to direct the Government's presently fragmented involvement with the air and water blankets that cover the earth. But the sparks it is generating are evident all over Washington.

**The anguish comes** from the numerous Federal departments and agencies that would have to give up part of their present domains to the newcomer. The Commerce Department would lose the Environmental Science Serv-

Some HEW officials question the propriety of the university getting into the act at all. "What's the basic research function of a university?" wonders Hiller. "Are diversions such as royalties consistent with its purpose?"

Prof. Murray Eden of the Massachusetts Institute of Technology and chairman of the National Academy of Engineering Subcommittee on Interaction with Industry goes further: "A university is not justified to say to a graduate student: 'If you go ahead with your work, there's a little money in it for you,'" he says.

Nevertheless, universities want a slice of the pie. The argument rests on the premise that the work was done at a university, by university personnel, with university equipment. They argue that a share of the royalties is needed to give university professors the incentive to work on drug projects.

**"We're not in it for the money,"** declares Richard A. Rossi, associate director of the office of research and project administration at Princeton University. "Any income to Princeton from patents and royalties over the years has been almost negligible, and is used to foster research."

Although the three-way impasse has been going on since the end of World War II, there are signs that the Government is bending in its position. The latest major sign before this week's HEW announcement came at the end of the Johnson Administration, when the Committee on Government Patent Policy of the Federal Council for Science and Technology suggested some further changes on patent policy.

Those recommendations, now being considered anew by the Nixon Administration, suggest that the Government grant qualified, long-term exclusivity where it deems fit.

ices Administration, the Transportation Department would lose the Coast Guard, even the Army Corps of Engineers fears that some of its coastal activities would be usurped.

The arguments are not new. They go back at least to 1884, when Geological Survey director John Wesley Powell tried to combine his agency into a single body including the Coast and Geodetic Survey, the Smithsonian Institution and the National Observatory. But, the pressure, measured by such things as the ballooning spending by private industry, is growing.

In 1966, a panel of the President's Science Advisory Committee recommended a major reshuffling that "would

place in a single agency all those Federal activities related to description, prediction, attempts to develop capabilities of modifying the environment . . . and those activities concerned with managing and developing resources of the ocean."

In 1968, the Commission on Marine Science, Engineering and Resources prepared a mammoth, 200-page report (SN: 1/18, p. 62) recommending a much more active future course for the country's oceanic endeavors—including a new agency.

The result is H.R. 13247. There have been such bills before, but this one differs in that it may have a chance.

One indication that NOAA's time may at last have come is the authorship of the bill. It was introduced by every single member—from both parties—of the 21-man oceanography subcommittee of the House Committee on Merchant Marine and Fisheries.

The subcommittee is devoting the month of October to hearings on the bill.

**So excited is** the private sector, in fact, that the National Oceanography Association, a private organization of industry and education officials, has published a press kit which supports the bill, but includes a pointed disclaimer that the new agency would be anything like the much-referred-to "wet NASA". The space program, says the Association's executive director Richard N. Rigby Jr., is "an all-Federal effort with a single objective requiring development of a new technology." By comparison, an oceanic program run by NOAA "will have a private investment larger than governmental outlays, will have multiple objectives . . . and will require improvement of old methods as well as new technological breakthroughs."

The star witness at the House hearings is likely to be Presidential Science Adviser Dr. Lee A. DuBridge, scheduled to appear on Oct. 21. He will represent the first on-the-record expression of the Administration's view of H.R. 13247.

In July, he said that "it is quite possible that an independent agency for oceanographic science and technology might be a good idea." But the problems of putting the idea into practice are at least enough to keep his support from being a foregone conclusion.

Nevertheless, the bill's supporters are not as gloomy as they have been in past efforts. "Generally I'm optimistic," says Thomas Clingan, counsel for the subcommittee. "I think that it has a good chance, barring any strong opposition from the White House. I'm encouraged by the fact that there has been no such statement." His committee,

which would get to oversee NOAA, is naturally more enthusiastic than are the Commerce and Interior committees, reluctant to see their constituent agencies lose a blooming plum.

Clingan's boss, subcommittee chair-

## RESEARCH FUNDING

### Dismay over foundations

Tax-exempt foundations in some instances have become tax havens for unscrupulous wealth. As a consequence, they have been included, to their despair, in a pending tax reform bill, passed by the House and now under examination by the Senate Finance Committee.

Scientists who depend on foundation support for their research fear that the Congress is in the process of throwing the baby out with the bath water.

"We should try to eliminate the disease and not the patient," Dr. Jonas Salk told the Senate Finance Committee, holding hearings this week.

Dr. Salk, whose research leading to the development of a polio vaccine was totally funded by foundations, feels that the foundation is as important to research as Government. "Foundations," he says, "can afford to be more concerned with the long-range future and Government, of necessity, is more concerned with the present and short-range future."

In another area, the funds for research in pollution and transportation control are currently largely supplied by foundation funds, according to Dr. J. R. Killian, chairman of the board of trustees of Massachusetts Institute of Technology. He contends that if the funds don't come from foundations, they won't be supplied at all.

**But the public** outcry against foundation abuses have produced the legislation which, if passed, could apparently inhibit foundations' support of research.

The reform act is unselective. It is equally harsh to all foundations.

The proposed 7.5 percent tax on foundations' net income, it has been estimated, would reduce foundation support of research projects by \$100 million per year. Added to reductions in Federal spending, such as the recently announced cuts in the Department of Health, Education and Welfare budget and the decreased research funds of the National Institutes of Health (SN: 9/20, p. 236), a severe shortage of research funds is a likely consequence.

Julius A. Stratton, chairman of the board of the Ford Foundation, spoke for both researchers and foundation heads when he stated, "We have found

man Alton Lennon (D-N.C.), believes that the bill may well pass the full House by the end of the calendar year. An identical bill has been introduced in the Senate, but hearings may not take place until spring. □

in the areas of science an alarming increase of organizations with financial problems."

And Dr. Killian, speaking of MIT's plight, pointed out that 80 percent of its building funds and 100 percent of its endowment are from private giving. "We have already begun to feel the effect of this proposed legislation," he says, "in decreased giving to MIT." Donors, he says, are afraid to contribute money and property they assumed to be tax-exempt which they may later have to pay taxes on.

## NEWS BRIEFS

### Defense, Draft, NSF

The military procurement authorization bill was the subject of lengthy and acrimonious debate in the Senate through the summer (SN: 8/16, p. 128). But the House passed its version of the bill last week under a stringent debate limitation that allowed members 45 seconds each speaking time.

The House bill grants \$21.35 billion, \$1 billion more than the Senate allowed. Of this, about \$7.5 billion will go for research and development.

The Senate bill had cut research money for offensive chemical and biological weapons (SN: 7/19, p. 47); the House required only periodic reports on CBW spending. The two versions must now be reconciled in conference.

**President Nixon** last week changed Selective Service procedures so that graduate students who are called up will be able to postpone induction until the end of the school year in which they were called. Previously they had been able to postpone induction only until the end of the semester.

**The House** this week passed a bill authorizing \$474.3 million in expenditures for the National Science Foundation—\$3.3 million less than the House Science and Astronautics Committee had recommended and nearly \$13 million less than requested by the Administration. Also approved by the same 384-to-5 voice vote was a provision requiring a college to deny grants to students found guilty by the college of rioting or convicted in a court of participating in or inciting a campus disturbance. □