

## 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