Hoechst makes deal with Mass. General

House panel examines overseas ties

Washington

University involvement with the commercial exploitation of genetic engineering is well on the way to becoming an issue between the United States government and the universities. Last week, at a meeting of Congressman Albert Gore's oversight subcommittee of the House Committee on Science and Technology, representatives of the Massachusetts General Hospital were hauled over the coals because of the hospital's agreement with Hoechst AG under the terms of which the German chemical company will provide \$50 million over the next ten years to run a molecular biology laboratory at the hospital, and will have first refusal of any patent licences that may result.

At the hearings, Dr Ronald Lamont Havers, Director of research at the hospital, demurred when asked to provide the subcommittee with a copy of the agreement it has signed with Hoechst. The subcommittee's chairman left the hospital and everybody else within earshot in no doubt of his belief that universities sustained for the past twenty years by federal grants should be careful not to give overseas enterprises favoured access to their expertise. There is now some talk that the subcommittee will subpoena the agreement between the Massachusetts General Hospital and Hoechst if the document does not turn up in the mail before too long.

The grant from Hoechst will be used to found a department of molecular biology at the hospital. Dr Howard M. Goodman of the University of California, San Francisco, will be the director of the enterprise, the staff of which is expected to grow to about 50 by 1983 and thereafter to 100. The hospital insists that the programme of research will be determined by the hospital alone, while the work of the department will be reviewed by a committee of six scientists independent of Hoechst. The operation of the agreement between the company and the hospital will be kept under review by a joint committee of three senior managers of the company and three trustees from the hospital.

The declared objective of the new department is to apply the techniques of molecular biology to the treatment of disease. The hospital says that all appointments in the new department will be made according to established academic procedures, that individual scientists will be free to publish how and when they choose provided that the hospital authorities are informed in advance, and that there will be no restrictions on collaboration with scientsts elsewhere.

According to the hospital, patentable discoveries will be patented by the hospital, and the benefits shared between the hospital and the inventor on the basis of existing rules. Hoechst will have a right to a licence to any patent springing from research which it has sponsored, while the royalty rate negotiated "will reflect the financial contribution of the company".

Two potentially contentious aspects of the agreement are that the company will be free to decide whether or not particular research projects should be funded out of the \$50 million set aside, and that members of the new department working on Hoechst-sponsored projects will not be free to consult with other companies. The agreement is automatically renewable if not terminated after ten years.

It has also been agreed that there will be a public seminar once a year to which some Hoechst scientists will be invited, and that the company will have a right to send up to four of its people to the hospital for training at any time.

Congressman Gore is unlikely to let these issues fade away. After last week's hearings, he said that "the questions that

NIH plan new overhead calculation

Academic research administrators will soon have to learn new algorithms for calculating how much overhead to charge against successful applications for research grants and contracts with the National Institutes of Health (NIH). So much is clear from the meeting last week (8-9 June) of the Institute's Advisory Committee, at which the task force led by Professor Samuel O. Thier of Yale University that has been brooding on the question of "institutional support" (bureaucratic jargon for overhead) promised to produce at the next meeting in October several proposals for reorganizing the present system.

Objections to the present system are several. Research grant proposals approved by study sections of NIH (the "peer review" committees) are made more costly by an amount negotiated between NIH and the recipient institutions intended to cover the cost of supporting the research concerned. On the average, NIH overheads cost 30 per cent of total expenditure on research grants and contracts. There are wide geographical variations, with the universities in the north-west of the United States successfully claiming larger percentages for institutional support than universities elsewhere.

The stimulus for the present review has come from federal agencies and universities, both equally appalled at the difficulties of carrying out the detailed accounting for research grant expenditure now required of them. But NIH also have an interest in heading off trouble about institutional support from the Reagan Administration, which has already shown its hand by removing from the NIH budget institutional support accompanying awards of postdoctoral fellowships.

The Thier task force plans to spend the summer assessing the merits of alternative mechanisms for providing institutional support. The favoured alter-

native to the present system appears to be the "fixed obligation" formula, under which research grants and contracts would be awarded on what is essentially a fixed-price basis, and on which federal investigation would be limited to a simple verification that direct and indirect costs have been properly incurred.

At the next meeting of the Advisory Committee in October, the task force will suggest that experiments should be carried out with several of the alternative methods of financial research projects. It is, however, unlikely that all the loose ends can be tied up by October — it is not, for example, at this stage clear whether the overhead element in fixed obligation grants should be assessed by a peer review committee and, if so, whether should be the appropriate study section.

Last week's meeting of the NIH Advisory Committee also wrestled a little inconclusively with the issue of patent rights in biological innovations.

One curious development to come to light was that many scientists are cheerfully ignoring the provisions of the Patents and Trademark (Amendments) Act of 1979. This legislation gives universities at which research grants are held the right to patent and exploit new developments, reserving to the federal government a non-exclusive right to a licence. Under the amended law, those holding grants from NIH are required to report all patentable developments.

These provisions have already been found unworkable in the development of monoclonal antibodies, each one of which may be potentially patentable. Given that a productive laboratory may expect to develop several hundreds of monoclonal antibodies a year, and that the cost of patent protection is a minimum of \$2,000, it seems to have been tacitly assumed that only those monoclonal antibodies likely to be commercially important deserve the investment of \$2,000-plus.

will confront our civilization as a result of genetic engineering" will be the most difficult ever, and that their solution will only be complicated if those responsible for original discoveries make commercial links with industry.

The subcommittee last week found a more congenial witness in Dr Donald Kennedy, president of Stanford University, who earlier this year was advocating a "second Asilomar conference" on the problems of universityindustry relationships. Kennedy, who more recently has been back-pedalling on this proposal, told the subcommittee last week of the ambivalence of research universities towards proposals for industrial support in the present climate of stagnant federal budgets. Well-ordered agreements, he said, could be beneficial, but he also pointed to the dangers of conflicts of interest, secrecy and the distortion of research training.

Universities are perhaps more than usually aware of these problems because of the advocacy of the virtues of industrial support for the research universities by the National Science Board.

Exploiting research

Stanford rules

Washington

A proposal for regulating the commercial activities of members of the Stanford University faculty is to be put to the Academic Senate at its meeting in September. One of the proposals is that members of the faculty should disclose details of consultancy agreements with commercial organizations if there are reasons to expect that conflicts of interest have arisen.

The new scheme has been worked out by a committee under Dr Ingram Olkin, professor of statistics and education at Stanford, which has recommended that the university should not invest in commercial ventures set up to exploit the results of research carried out at Stanford "if any current Stanford faculty member participates" either as a shareholder or as a manager. Similarly, the university would not accept stock in such a company as part of a licensing agreement.

The proposals have been stimulated by the recent interest in the commercial exploitation of genetic manipulation, to which several members of the Stanford faculty are in a position to contribute. But it is acknowledged that similar problems may arise in other fields, the development of computer software for example.

The case for a distant relationship between the university and commercial enterprises in which faculty members are involved is based on the fear of the conflicts of interest that could arise in making faculty appointments and promotions, allocating space and settling faculty salaries, the danger that graduate

Yugoslavs to resign

Dr Pavle Savic, President of the Serbian Academy of Arts and Sciences since 1971, has resigned in protest against the conduct of recent elections to the Academy. His resignation, which takes effect from the academy meeting of 28 May, came as no surprise — it had been openly discussed in the Yugoslav press for the preceding three weeks.

According to Dr Savic, he resigned because of the election of someone who had served several years' rigorous imprisonment as a "cominformist". He had been informed of this one month before the elections. On checking the allegation and finding it true, Dr Savic notified the appropriate Academy officials. But the election went ahead and the "cominformist" was elected. The next day, Dr Savic announced his intention to resign. Two vice-presidents and the general secretary of the academy also resigned; they, however, will serve out their full term of office (until the end of the year) to maintain continuity of the academy's activities.

Dr Savic's walk-out, seven months before his term of office ended, is widely seen as a protest, not merely against the election, but against the prevailing atmosphere in the academy. A physicist, he had hoped, to build up the research side of the academy, concentrating on modern trends including laser physics, solid-state electronics and molecular biology. He was particularly keen to bring in younger scientists into the academy's institute. Most members, however, showed little enthusiasm for his plans.

education might be distorted and the possibility that the university's external reputation might be affected adversely.

The committee also advocates a change in the method by which the rewards from agreements for the licensing of patents are shared out. At present, if Stanford research leads to a patent, the income is divided equally between the researcher, his or her department and the university as a whole. It is now suggested that if the income from some invention should exceed one half of a department's annual budget, the two-thirds of the royalty income not due to the inventor should be paid into a research fund from which all departments at Stanford could hope to benefit.

The committee has obviously been cautious, perhaps even overcautious, in its approach to consultancy agreements. At present, academics are required to disclose the amount of time they spend in this way, which must not exceed 13 days a quarter. There is no mechanism for monitoring this gentleman's understanding. In future, if the faculty agrees, faculty members may have to disclose who they work for, and for how long.

Tropical disease finance

World Bank acts

After a plea by Mr Robert McNamara, who resigns as president of the World Bank on 30 June, the bank governors are expected to agree this week to contribute \$2.48 million (£1.25 million) to the Special Programme for Research and Training in Tropical Diseases (TDR) of the World Health Organization (WHO).

Previously, the bank has been willing to act merely as a financial adviser and banker to TDR, as one of the programme's three co-sponsors. (The others are WHO and the United Development Nations Programme.) The bank's main concern is with development loans, and it has been exploring for more than a year how to refine its policy towards the direct support of research. That review is not complete, but McNamara thought it well enough advanced that a commitment should now be made to the tropical disease programme. He carried his executive board with him, and their recommendation has now to be approved by the governors — the nations which fund the bank. There is not expected to be any opposition.

The support for TDR comes at an opportune time. First firmly established in 1977, and dealing with six diseases - malaria, schistosomiasis (bilharzia), trypanosomiasis (sleeping sickness), leishmaniasis, leprosy and filariasis — TDR's funds first grew rapidly but have now become roughly static at about \$24 million (£12 million) a year. Moreover Britain, which was contributing around £600,000 a year (but actually received back more in research grants, according to WHO), announced last December that it could not pay its 1981 contribution - shocking the 25 other contributing governments, many of which see little or no return in terms of research carried out in their countries.

According to the Canadian chairman of the TDR Scientific and Technical Advisory Committee, Dr A. B. Morrision, the effectiveness of the programme could be "crippled in the short term" if inflationary pressures are not compensated for; and in the long term, additional resources must be mobilized to permit large-scale trials of new tools for prevention and treatment now being developed.

Even so, Britain's contribution to TDR for the present year is definitely cancelled, says the Overseas Development Administration (ODA). And although next year's is "under review", the ODA's £1,000 million of aid money this year will fall by 5 per cent a year for the next three years, making a recovery of the TDR contribution less and less likely. This should not be taken as an implicit criticism of TDR, say ODA officials. On the contrary, the programme is the best managed of all the WHO special programmes, they say, thus putting a cloud

over the two remaining programmes still