functional DNA", and describe the various steps used to cleave viral or circular plasmid DNA, insert a separate DNA fragment, and grow up and separate unicellular organisms containing the altered DNA.

Still awaited is a decision from the Patent and Trademark Office on a second application made by the two universities on behalf of Dr Cohen and Dr Boyer, which covers any organism produced with the techniques covered in the first patent.

Mr Reimers said last week that, from the universities' point of view, this was likely to be the more important patent, since without its protection companies could manufacture products abroad using the recombinant DNA techniques, and subsequently sell them in the United States without having to pay royalties.

The Patent Office's decision on the second application is expected within a year. All such patent applications covering microorganisms had previously been held up pending a ruling from the Supreme Court, which decided in the summer that there is nothing in existing patent law which denies microorganisms protection.

Meanwhile, the University of California has filed a suit against the pharmaceutical company Hoffman LaRoche and the San Francisco firm Genentech, claiming that the two companies must pay damages to the university for the use of a cell line produced by university scientists which the companies have been developing as a potential commercial source of interferon.

The scientists at the University of California, Los Angeles who produced the cell line claim that it was passed to Hoffman LaRoche without their permission. But in the counter-claim Hoffman LaRoche is arguing that there were no conditions attached to the cell line when it was obtained indirectly through a researcher at the National Cancer Institute, and that the company therefore has no obligation to the university.

David Dickson

Genetic engineering

Hormone growth

Genentech, the California-based biotechnology company, will begin clinical trials of its latest genetically-engineered product, human growth hormone (HGH), in London this January. But Genentech's industrial partners in the venture, Kabi Vitrum AG of Sweden, are somewhat ambivalent about the development.

Kabi Vitrum is the major world producer of HGH, made at present from cadaver pituitaries. The hormone is used to treat HGH-deficient children, reckoned to be some 7–10 per million of population. But the nature of the source naturally limits production, and Kabi estimates the true market to be three times the present supply; so the firm searched for other sources. Genetic engineering was an obvious possibility, as HGH is a small peptide, about the size of insulin.

So in 1978 Kabi asked Genentech to produce a strain of *Escherichia coli* containing the HGH gene. Under the contract, Kabi would have sole world production rights, except in the United States and Canada, where they would be shared with Genentech. But Genentech was successful sooner than Kabi expected, and further surprised the firm by making rapid preparations for commercial production. Genentech had been expected to stick to research.

Now Genentech is well ahead with pilot tests in 700-litre fermenters, while Kabi has been restricted to 10 litres by Swedish limits on scale-up of genetic engineering experiments; and Genentech plans clinical trials at Great Ormond Street Hospital for Sick Children starting in January 1981. Kabi, meanwhile, would wish to be more cautious. "We do not know about Genentech's toxicological testing" said Dr Bengt Karlsson, Kabi's managing director, "but we would not wish to put the product on clinical trial for at least six months". Nor is Kabi's caution due to lack of material, for they have access to Genentech's supply.

However, in London, where Dr James Tanner at Great Ormond Street will conduct the trial, it is felt that Genentech's toxicity testing has been quite sufficient. There have been plenty of animal and monkey tests, says Dr Tanner, and the UK Department of Health has passed the material for clinical trials. The Genentech HGH will be given to 20 patients for a year, 10 of them first treatments, and the other 10 already three years into a course of pituitary HGH. The main contaminant will be 1–2 per cent of bacterial protein; and the danger is that HGH-like proteins in this material may induce antibody formation to true HGH.

Dr Tanner welcomes the new source of the hormone. In the United Kingdom there are 100 new cases a year of HGH-deficiency, and just enough pituitary HGH to go round (produced from 60,000 cadavers a year). But it is always "touch and go" each year whether sufficient cadavers will be made available. Moreover, if there were more HGH around, it could be tried out on more marginal cases of delayed growth, or slow bone healing after fractures.

Ultimately, Genentech will not be the source of HGH in Britain. Kabi announced last week that it has concluded a deal with the Department of Health for the Centre for Applied Microbiological Research at Porton Down to conduct scale-up trials on the Genentech bacterium. In exchange, Kabi will offer the product at a preferential price to the Department of Health, and assist Porton with its present production of HGH from pituitaries. (Kabi believes it has a more efficient extraction system.)

The centre is seeking permission from the Genetic Manipulation Advisory Group to ferment the engineered *E. coli* in 400-litre vats; and to satisfy GMAG, it must show that the organism is killed in the closed fermenter before the material is extracted.

Despite early misgivings, the Department of Health has begun to encourage Porton to become involved with industrial applications of the recombinant DNA technique — Unfortunately nothing has yet come forward in the United Kingdom that fits the bill. Dr Peter Sutton, director of Porton, is delighted at the deal with Kabi: "It means we can get our feet wet" with commercial scale genetic engineering, he said last week.

Robert Walgate

US Administration

Reagan's men?

Washington

President-elect Ronald Reagan's transition staff is sifting through the list of candidates for top-level positions in the new Administration, and the names of the first cabinet appointments should be announced this week. Potential choices have been widely discussed in the press — often names intentionally leaked to gauge public reaction — so few major surprises are expected.

Top candidate for the renamed Department of Health and Human Services (DHHS), responsible for the biomedical research budget of the National Institutes of Health (NIH), is Senator Richard Schweiker, Mr Reagan's running mate in his bid for the 1976 Republican nomination.

Mr Schweiker gave up his Senate seat earlier this year to work for Mr Reagan's election. In the Senate he was an active member of the Labor Committee's health and scientific research subcommittee, and as ranking minority member often supported the initiatives of the committee's present chairman, Senator Edward Kennedy.

Mr Schweiker is "definitely pro-science", one NIH official said last week, although adding that he had received some criticism for inserting in the institutes' funding legislation a clause that requires special arrangements for supporting research in diabetes and digestive diseases — the type of constraint that NIH prefers to work without.

The appointment would be less popular with labour unions, since Mr Schweiker is the sponsor of a bill designed to restrict the activities of the Occupational Safety and Health Administration.

As DHHS Secretary, Mr Schweiker would be responsible for the budget and activities of the National Institute of Occupational Safety and Health, part of the Center for Disease Control.

A predecessor in that post, Mr Caspar Weinberger, is widely tipped as next Secretary of Defense. He was director of the Office of Management and Budget under President Nixon, where his financial

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stringency earned him the nickname "Cap the Knife". He was later promoted to Secretary of the then-named Department of Health, Education and Welfare at a period when biomedical research was becoming dominated by a congressional "disease of the month" approach.

Various names are being discussed for the position of Under-Secretary of Defense for Research and Technology, responsible for the Pentagon's massive research budget. They include Mr William van Cleave, at present head of Mr Reagan's defence transition team, and Mr Benjamin T. Plymale of the Boeing Corporation, who was the source of controversy last year when his security clearance was temporarily revoked.

No clear candidate has yet emerged to head the Department of Energy. One suggestion, Mr Michel Halbouty, a Houston oilman and geologist who was Reagan's chief energy strategist during the campaign, is being opposed by some influential Republicans because of his lack of government experience. Others have opposed the nomination of Mr Frank Zarb, a top energy official in the Nixon and Ford administrations, because of his involvement in setting up the present system of price controls on crude oil and gasoline. Two possible contenders are Dr John Sununu, professor of engineering at Tufts University, Massachusetts, and Representative Clarence Brown of Ohio.

Appointments at a lower level, including the heads of independent agencies such as the National Aeronautics and Space Administration, are not likely to be announced until the main cabinet posts have been filled.

In the science field, these appointments will also depend on the report of the science and technology transition team under Dr Simon Ramo of TRW and Dr Art Bueche of General Electric.

Dr William A. Nierenberg, director of the Scripps Institute of Oceanography, is widely mentioned as possible director of the Office of Science and Technology Policy (OSTP), as is Dr Guyford Stever, ex-director of the National Science Foundation, who held the OSTP job for a few months at the end of the Ford administration.

At the National Science Foundation (NSF) itself, the Reagan administration seems unlikely to overturn the appointment of Dr John Slaughter as director. Dr Slaughter was sworn in two weeks ago, and that the emphasis that he is keen to put on the development of engineering and applied research should match Republican goals for science.

Finally, the appointment of Dr Frank Press, the present director of OSTP and President Carter's Science Advisor, was assured as the next president of the National Academy of Sciences when nominations for the post closed last Monday without any other names having been put forward. **David Dickson**

Soviet plans

Science on tap

Soviet science is to be geared even more closely to the needs of the economy, according to the guidelines for the 11th Five Year Plan, published last week. The plan calls for a substantial reduction in the time taken to disseminate research results, strengthening of the links between research and production, better coordination between scientific establishments and an improved basis for scientific planning.

Individual research priorities specified by the guidelines range from the immediately practical (the improvement of computer technology and software) to the long-term (creation of the bases for thermonuclear power engineering), and from the further conquest of space to greater environmental protection and economic utilization of the biosphere. Biotechnology to produce new compounds with tailor-made properties, particle physics and immunology all receive special mention.

At this stage of planning, however, no specific targets are mentioned, nor is the financing of science discussed. The emphasis on closer links between science and industry, however, and the statement that ministries and departments are to bear increased responsibility for industrial research may have some financial implications. Their responsibility will presumably also include the planning of research in institutes under their control. One of the main complaints of Soviet scientists in recent years has been the inflexibility of research plans once approved. The new guidelines, however, urge that the direction of research and development should be "determined in good time . . . and changed to meet the demands of the scientific-technological revolution".

All this, however, depends on an overall increase of labour productivity. In industry, this increase is specified as 23–25 per cent, which is to account for more than 90 per cent of the increase in output. For the scientists no such target is set, perhaps because the recent "press debate" in *Literaturnaya Gazeta* has revealed only too clearly how much scientists resent having their intellectual performance monitored.

Vera Rich

DNA guidelines

Bowing out

The US National Institutes of Health (NIH) are facing a virtual revolt from local Institutional Biosafety Committees (IBCs) over whether there is still a need for strict surveillance of research using recombinant DNA techniques.

At a meeting in Washington organized by the National Institute of Allergy and Infectious Diseases, the predominant view of the chairpersons and representatives from more than 150 IBCs throughout the country was that the prime role of the IBCs has become largely a public relations exercise.

Few of those attending the meeting were prepared to accept that recombinant DNA research presented any greater health or environmental hazard than work with unaltered organisms not covered by the NIH guidelines.

Many complained of the amount of paperwork they are required to carry out, particularly in the light of recent revisions of the guidelines, which have shifted most of the responsibility for reviewing research protocols from the NIH's Office of Recombinant DNA Activities to the local level.

The Washington meeting had originally been called for IBC chairpersons to discuss how their committees were operating. But the main focus of the two-day meeting rapidly became whether the IBCs — or even specific regulations covering recombinant DNA research — were any longer needed in their present form.

According to one NIH official, the mood of the meeting was that the amount of time that IBCs put into DNA issues was out of proportion to all sorts of other biohazards.

One recommendation being forwarded to next month's meeting of the NIH's Recombinant DNA Advisory Committee is that all experiments using the disabled K12 strain of the bacterium *Escherichia coli*, or the yeast *Saccharomyces cerevisiae*, as host–vector systems should be totally exempt from the guidelines.

In the case of *E. coli*, the same suggestion was made last year, but the advisory committee then recommended — and NIH director Dr Donald Fredrickson agreed — that although prior approval was no longer necessary for such experiments, the requirement that the experiments be carried out under P1 physical containment conditions should remain.

Members of biosafety committees also complained about the additional paperwork resulting from NIH's requirement that, although details of all approved experiments no longer have to be registered, they must keep detailed records of all recombinant DNA work carried out in their institutions.

The latter requirement was partly the result of a survey at Stanford University in California which showed a discrepancy between the rate at which different committees required experiments to be reclassified, possibly indicating that some were interpreting the guidelines more strictly than others.

But the IBC members baulked at yet more paperwork.

A straw vote taken during the final plenary session of the meeting revealed little support for the proposal that NIH should keep a record of all recombinant DNA research carried out under the guide-

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