

Biotechnology

Cohen-Boyer patent finally confirmed

Washington

AFTER 10 years of legal argument, Stanford University has finally been granted a "groundbreaking" product patent covering recombinant DNA molecules as produced by the Cohen-Boyer gene cloning technique. The Cohen-Boyer technique is fundamental to most genetic engineering research, and the new patent, which includes the uses of recombinant DNA in bacterial cells, confirms Stanford's proprietary hold on the fledgling biotechnology industry. A process patent covering Cohen-Boyer was granted to the university in 1980, and is considerably strengthened by the new product patent.

At present 66 companies are licensed to use the technology by Stanford, which shares rights with the University of California at San Francisco. Others have been holding back from paying the \$10,000 annual licence fee until the status of the product patent became clear. The university will from now on enforce both, and it is likely that most industrial users of the technique will pay up: as one patent attorney put it, "you'd have to be out of your mind to challenge a \$10,000 licence" since legal costs would inevitably be much greater than the licence fee.

The Cohen-Boyer technique uses a bacterial plasmid to transfer foreign DNA into a host cell. While the cost to licensees of using the technique might be modest, the value of the patents to Stanford and the University of California, San Francisco, is likely to be considerable, especially when genetically engineered products become more widely available. The universities will share royalties at the rate of 1 per cent for the first \$5 million of sales, decreasing to ½ per cent on sales over \$10 million. Use of the Cohen-Boyer technique in pure research is not restricted, but the partners have already earned almost \$3 million on the process patent from commercial companies. The two inventors, Dr Stanley Cohen of Stanford's school of medicine and Dr Herbert Boyer, professor of biochemistry at the University of California, San Francisco, have both waived their rights to a one-third share of revenues. The income is used by the universities to support graduate student programmes. The new patent will prevent, for example, companies avoiding royalty payments by manufacturing abroad and importing into the United States.

The Cohen-Boyer saga has been controversial on several counts. In 1982, the Patent and Trademark Office tentatively rejected the product patent on the grounds that the original application incorrectly

specified the origin of the plasmid called pSC101. The plasmid was described in the application as arising from a naturally occurring plasmid by recircularization of a fragment itself produced by hydrodynamic shear. A later paper by Cohen and a co-author revised this view and left open several possibilities for the plasmid's origin.

A patent specification must under US law provide sufficient information to enable a person "skilled in the art" to reproduce the invention. In granting the new product patent the patent office seems to have recognized that a description of how to make a product contains sufficient disclosure if it is operationally accurate, even if the proposed interpretation is incorrect.

Also related to the disclosure requirement was the objection that Cohen and Boyer failed to deposit samples of their plasmid in a public repository at the time the application was filed. They did, however, make samples available to

qualified investigators, and the patent office seems now to have accepted that this practice was not unduly restrictive. This aspect of the case has caused some consternation to lawyers, who see dangers in allowing an organism in a private repository to suffice as a patent standard. Not least of these dangers is the natural inclination of a scientist to replace a strain isolated for a specific purpose with a better specimen should one turn up.

Other issues raised have included that of whether the invention was non-obvious and whether the scope of the application was too broad. Despite some fleeting references to the possibility of artificially recombining DNA published more than a year before the application, the new ruling confirms the originality of the idea. Stanford has withdrawn an earlier claim over the use of recombinant molecules in eukaryotic cells to expedite the present patent, but is still pursuing that claim in a separate undisclosed application.

The patent office usually declines comment on interpretation of its decisions, although an official said the judgement did "not represent a change of policy". A detailed policy statement on biotechnology is now being prepared by the patent office and is expected to clear up much of the confusion left in the wake of the Cohen-Boyer patent.

Tim Beardsley

Industrial training

Britain lags well behind

A NEW approach to vocational training and education in Britain is essential if British industry is to compete successfully in world markets. This is the major conclusion of a report entitled *Competence and Competitions* prepared by the Institute of Manpower Studies for the National Economic Development Council (NEDC) and the Manpower Services Commission which compares, for the first time, British investment in training and human resources with that of West Germany, Japan and the United States. All three of these countries clearly recognize education and work competence as an important key to their economic success, some major companies in Japan and the United States, for example, investing between 2.5 per cent and 3 per cent of their sales revenue in training.

Young people in Germany, Japan and the United States are better equipped for working life than their British counterparts, the report says, because more of them participate in education and training programmes and for longer periods. In Japan, 84 per cent of school leavers voluntarily continue their education to the age of 18, in Germany the figure is 70 per cent, and in the United States 73 per cent of those aged between 16 and 24 are enrolled in some form of further education. It is quite sobering to realize that, in Britain, education beyond 16 is the exception rather

than the rule; two-thirds of all 16 year olds enter the labour market.

Britain trains only 15,000 graduate engineers a year compared with Japan's 70,000. But, the report says, the most acute shortage is among craftsmen, technicians and middle-level engineers, and Britain must counteract the decline in apprenticeship training by creating alternative training routes.

Education and training in Germany, Japan and the United States is funded primarily by industry. In Germany, for example, employers bear 80 per cent of the cost of the 1.67 million apprentices under training. All three countries have responded to the recession by accelerating their training programmes and so investing money in the future.

The report makes twenty-four specific recommendations. Among other things, it calls for measures to enable 80 per cent of young people in Britain to enter the job arena with qualifications relevant to their employers and for Britain to emulate Germany's achievement of having 12 per cent of its adult workforce on work-related education and training. Industry, it says, must take the responsibility for funding new engineering training facilities. The report calls on the government, trade unions and employers to make a positive commitment to these aims.

Marcus Chown