Cetus retains PCR patents

San Francisco

CETUS Corporation has finally nailed down its lucrative patent on the revolutionary polymerase chain reaction (PCR) technology. Last week, a US District Court upheld the validity of the patents granted to the biotechnology company against a challenge by the chemical giant Du Pont.

Although the decision came as no surprise to biotechnology observers, it was nonetheless welcome news to Cetus, whose financial health depends in large part on its rights to the PCR technology. The victory was especially important to the company in the light of the major blow it received last summer, when the US Food and Drug Administration unexpectedly failed to recommend market approval for interleukin-2, its anticancer drug.

The six-week jury trial, which included testimony from three Nobel laureates, examined the origins of PCR, a 'gene amplification' technique. PCR is basically a method of detecting and serially reproducing specific gene fragments from a pool of DNA. It has dramatically transformed many areas of biological research since its introduction in 1985, and has also been used to identify criminals from blood samples, examine archaeological remains and diagnose infections and diseases.

In the trial, Cetus maintained that PCR was invented by its scientist Kary Mullis and was not practised anywhere until Cetus announced it in a 1985 paper. Cetus's patent rights to PCR were first issued in 1987, and were confirmed by a US Patent and Trademark Office re-examination last year.

Du Pont, however, contended that the process was made obvious by the work of Massachusetts Institute of Technology professor and Nobel laureate H. Gobind Khorana and his colleagues in the early 1970s. Two of Khorana's papers and a grant application were presented as evidence by Du Pont, although Khorana declined to testify.

Instead, Du Pont presented as witnesses Stanford University Nobellist Arthur Kornberg and several of Khorana's postdocs from the 1970s, while Cetus countered with testimony from Nobel prizewinners Hamilton Smith of Johns Hopkins University and Sir Aaron Klug of the UK Medical Research Council.

A Du Pont attorney said last week that the company is "reviewing all its options" regarding the decision. A separate phase of the trial, scheduled to begin next week, will consider the Cetus countercharge that Du Pont has infringed upon another PCR-related patent; in that phase, Cetus will seek damages from Du Pont as well as an injunction against Du Pont sales of materials it considers to be PCR technology.

The markets for PCR technology are expected to grow enormously in the next few years. A Cetus joint venture with Perkin-

Elmer Corporation, which sells PCR equipment and reagents to research laboratories, resulted in sales of \$26 million last year. In addition, Cetus has licensed PCR to Hoffmann-La Roche and others to develop diagnostics kits which may be used for a variety of medical purposes including detection of cancers, AIDS and genetic disorders, as well as for forensic identifications. Analysts estimate that the combined PCR market may reach \$400 million within five years.

Now that Cetus's rights to that market appear safe, Cetus attorney Peter Staple believes the victory has implications for other biotechnology firms as well. "Patents can be an equalizer", he says. They can allow young, relatively small companies to protect their results from big corporations in the still-unpredictable field of biotechnology.

Elizabeth Schaefer

CITATION ANALYSIS

US science OK

WHILE US science advocates argue that US science is losing ground to the rest of the world, new data from the Institute for Scientific Information (ISI) appear to suggest otherwise. During the past decade, the United States has not only improved nearly 7 per cent in the relative quality of its science (as measured by average citations per US paper compared to the worldwide average), but is also improving faster than any of the other Group of Seven (G-7) nations. The data also show an apparent correlation between funding and science quality. Research budgets in the United States, Japan, Germany and France — whose research has improved relative to the rest of the world — have consistently grown over the decade, while Britain and Canada — whose research quality has slipped over the past five years — have been hit by budget cutbacks.

Research quality of the G-7 nations, expressed as percentage change in citations per paper from 1981-85 to 1986-90, relative to the world average in both years. Source: ISI.

Education under threat

London

THE quality of UK undergraduate education will be damaged if the Universities Funding Council (UFC) continues to insist that universities take on more students, despite the fact that not all of these will be funded, warns the Committee of Vice-Chancellors and Principals (CVCP).

The UFC said last week that it will fund 303,700 undergraduates in 1991-92, some seven per cent more than in 1990-91. But the universities' four-year plans, submitted to the UFC last summer, had requested

Sir Peter Swinnerton-Dyer — grant calculator.

335,000 students in 1991-92. A covering letter from Sir Peter Swinnerton-Dyer, chief executive of UFC, sent to each university to explain how its grant had been calculated, says that the UFC expects universities to admit significant numbers of students without funding from the UFC. Most vice-chancellors regard this as a thinly veiled threat. They say that universities that refuse to expand will be discriminated against in future years when the UFC comes to distribute its budget.

Sir Edward Parkes, chairman of the CVCP, says that this unfunded expansion will mean a decline in the quality of UK undergraduate university education. His comments reflect the official position adopted by the vice-chancellors at their meeting last Friday. But Sir Graham Hills, from Strathclyde University, a long-standing dissident in the vice-chancellors' ranks, says that universities have been claiming for ten years that underfunding will produce an imminent decline in undergraduate education.

Most vice-chancellors accept that the government is unlikely over the next few years to give the UFC sufficient money to fund the desired expansion in full. Last autumn, there was much speculation that some universities would be forced to charge students 'top-up' fees to maintain teaching quality. This would be extremely unpopular with students, and Hills believes the 'political odium' of fees will deter universities from introducing any charges for at least another year. Sir John Kingman, vice-chancellor of the University of Bristol, says the opposition to top-up fees, from the government, as well as from students, means they are unlikely for the 'foreseeable future'.

British university funding has been shrouded in uncertainty since last autumn,