Europe approves first transgenic animal patent

- Decision could spur EC patenting
- Activists mobilise to challenge ruling

Brussels

THREE years after the US Patent Office granted the world's first patent for a genetically engineered animal — Harvard University's transgenic 'oncomouse' — the European Patent Office (EPO) has decided to go the same way. Although opponents of animal patenting promise to challenge the EPO ruling, the move will give added impetus to a European Commission directive, now being considered by the European Parliament, that would legalize animal patenting in the 12 European Communities (EC) states (See *Nature* 353, 8; 5 September 1991).

The oncomouse was developed in 1984 by Philip Leder and Timothy Stewart, then both at Harvard University. It carries several genetic sequences containing mouse oncogenes and promoter regions, and so is extremely susceptible to tumours, making it a useful model for studying cancer. But Harvard's patent application was worded sufficiently broadly to cover all transgenic mammals containing activated oncogenes. The new European patent applies to 11 of EPO's 14 member countries, including the influential 'big four' EC members — Britain, France, Germany and Italy — plus four other EC nations.

While the US patent office moved fairly quickly to grant a patent, Harvard's European application has been the subject of bitter controversy, and has languished in EPO's Munich office since 1985. In 1989, EPO patent examiners rejected the application, arguing that the European Patent Convention prohibits the patenting of animals (see *Nature* 340, 85; 13 July 1989). But after a successful appeal by Harvard, the examiners were last year told to reconsider their decision, and to weigh the benefits to cancer research of granting the patent against the likely suffering of the tumour-susceptible animals themselves.

Opponents of the decision now have nine months in which to issue a formal challenge. "The case is very likely to continue," says EPO spokesman Rainer Osterwalder. And, indeed, a coalition of European animal welfare groups, headed by the British organization Compassion in World Farming, is already planning to fight the decision.

Compassion in World Farming is concerned that the oncomouse ruling will clear the way for the patenting of transgenic farm animals. Among a number of transgenic animal patent applications be-

ing reviewed by EPO is a request from Merck and Co. for a patent on a chicken carrying the gene for bovine growth hormone. Compassion in World Farming's legal director Peter Stevenson argues that such a rapidly growing chicken is likely to suffer excessively from leg and foot deformities.

Stevenson's challenge will be made under an article of the European Patent Convention that can deny a patent if the invention is deemed to be "contrary to public order or morality". He believes that concern over the welfare of transgenic animals justifies a challenge on moral grounds. But Norman Davies, head of patents with the British Technology Group, says he knows of no case in which the 'public order' clause has been used successfully to challenge a patent.

Despite the probable challenge, the EPO decision to grant the oncomouse patent will boost the prospects of a European Commission directive on biotechnology patents that would make legal the patenting of transgenic animals throughout the EC. First proposed in 1988, the directive has struggled to find time on the European Parliament's agenda, and was recently rejected by the Parliament's Agriculture Committee.

But Commission biotechnology officials are now optimistic that the Parliament's Legal Affairs Committee, which has the lead role in advising the full Parliament on the issue, will recommend that the directive be accepted. That committee is due to vote at the end of this month, and is expected to allow the patenting of transgenics, although it may ask for some restrictions to ensure animal welfare.

Assuming the directive passes, the full Parliament may vote on the directive as early as next month, after which the language would be sent to ministers of the EC member states to be formally adopted.

Commission biotechnology officials hope the latest developments in the Parliament, together with the new EPO decision, will provide the right climate to press forward quickly with the new directive. The directive contains a range of provisions to harmonize the patenting of biotechnology products across the EC and, with the 'single European market' just over one year away, Commission officials would like to see the directive enforced as soon as possible.

Peter Aldhous

Green light for ddI

Washington

AFTER an expedited review of just six months, the US Food and Drug Administration (FDA) gave the New York-based drug company Bristol-Myers Squibb approval to market its antiretroviral drug Videx (also known as dideoxyinosine or ddI) for the treatment of AIDS. The drug, approved initially for narrow use, can be used to treat both adult and paediatric AIDS patients who are intolerant to AZT, the only other approved drug for the treatment for HIV infection.

Under an expanded access programme and through clinical trials, the company estimates that more than 30,000 patients have already received VIDEX therapy. After a review of preliminary phase I trial data, the drug was approved on the basis of ddI's effect on increasing the patient's CD4 helper cell count, a surrogate marker for determining clinical effectiveness.

Donald Abrams, an AIDS researcher at the San Francisco General Hospital and a member of FDA's antiviral drug products advisory committee which recommended approval of Videx, says that while ddI clearly has biological activity, he would be happier if HIV patient survival rates were as encouraging as their improvement in CD4 counts after treatment with the drug.

The company, which estimates that a year's supply of Videx will cost about \$1,745, has set up a reimbursement assistance programme to help patients identify sources of third-party reimbursement.

Diane Gershon

Challenge to AZT

New Delhi

INDIA is the latest country to challenge the Burroughs Wellcome monopoly on AIDS drug AZT. Three Indian pharmaceutical companies expect to sell the drug on the domestic market and for export before the year's end.

The Indian Institute of Chemical Technology (IICT), which developed the process for synthesising AZT, has licensed the process free of cost to Lupin, Cadila and Reddy Laboratories. According to Dr. A.V. Rama Rao, director of IICT, the Indian-made AZT will cost a quarter or less of the current Wellcome prices.

The fact that AZT has been at the centre of patent disputes in the United States and Canada does not affect India, which has not signed the Paris convention and does not recognize patent protection for pharmaceuticals. Under Indian patent law, only processes, and not products, may be patented. Several Indian companies are exploring the foreign market in Africa and other areas where Burroughs Wellcome has no patent. The World Health Organization has shown interest in the Indian product and may become the largest buyer, Rao says.

K.S. Jayaraman