Patent fights over hepatitis C test kits reverberate around the world

Sydney. Australia has become the latest battleground in a continuing and acrimonious conflict over patents awarded to the US biotechnology company Chiron Corporation of Emeryville, California, covering the rights to the DNA sequence of hepatitis C virus (HCV) and to tissue cultures and vaccines developed from that sequence.

The patent has been controversial since Chiron first applied to patent offices around the world for patent protection for its hepatitis C screening kits in November 1987. Since then Chiron has been awarded patents in various countries, including Australia, Germany, the Netherlands, Japan, the United Kingdom and Japan, although the US patent has not as yet been granted.

But the breadth of the patent remains

sharply contested. Scientists in Australia, for example, where Chiron is suing one of its competitors, International Murex Technologies Corporation, for infringing the patent, claim that the granting of the patent is already hampering research on the virus.

Last week, Stephen Locarnini, head of the Victorian Infectious Diseases Reference Laboratory at Fairfield Hospital in Melbourne, Victoria, said that one sponsor had pulled out of a research project after inspecting the Chiron patent.

Locarnini admits that the resulting shortfall in funds had been made up through another programme. But he adds that the patent granted to Chiron is so broad that it is difficult for small investors to put money into research on the hepatitis C virus. Australia is not the only country in which legal battles are being fought. Last month, for example, Organon Teknika nv, a division of the Dutch multinational chemical company Akzo Nobel nv, announced an appeal against a court injunction stopping it from distributing hepatitis screening kits until a full hearing has been held of charges of patent infringement brought against it by Chiron.

The order was made by the Hague district court at the demand of Chiron, following last year's award of a patent to Chiron by the European Patent Office. The patent application had been strongly contested by Organon Teknika, which imports HCV test kits made by the US company United Biomedical Inc.

Organon distributes kits in the United Kingdom, the Netherlands and Germany, and is being sued by Chiron in each of these countries. Murex is also being sued by Chiron in the United Kingdom and Italy, as well as Australia, over its anti-HCV test, manufactured by its subsidiary, Murex Diagnostics. Murex says that, like Organon, it is seeking to have Chiron's HCV patents revoked.

The Australian patent, which is similar to that filed in most other countries, contains more than 30 clauses. The first of these covers most of the DNA sequence for the HCV, while the remainder cover techniques for tissue culturing and vaccine development from that sequence.

Larry Kurtz of Chiron claims that, without the reward offered by the patent system, it is doubtful whether companies such as Chiron would make the substantial investments needed to solve the problem posed by the HCV.

The case against Murex for violation of Chiron's patent is expected to come to court in Australia in the middle of next year. Chiron has already won a similar challenge to its patent in the United Kingdom during hearings on suits filed against both Murex and Organon Teknika.

An initial hearing resulted in the patent being ruled as valid, except for clauses on tissue culturing and vaccine development which were subsequently removed from the UK patent. A second hearing resulted in a decision that the defendants had infringed the patent. The final hearing is due to take place in November, when Chiron expects to be awarded damages against the defendants, and an injunction stopping the distribution of their products.

But the defendants still intend to appeal, arguing that the patent is invalid because it is in the public interest to allow more than one company to market HCV tests.

Mark Lawson

Strasbourg goes for top potential

Paris. The dream of school physics classes everywhere, the world's largest Van de Graaff generator (see right), built at a cost of FFr100 million (US\$18.5 million) and planned eventually to generate a potential of 35 million volts (MV), opened last month at the Centre de Recherches Nucléaires in Strasbourg, France.

But although the cost of the so-called Vivitron may have raised some hairs, the main aim of the

machine is to study the structure of atomic nuclei by accelerating ions. Indeed, Strasbourg believes the new machine will reinforce its ambition to become the European centre of excellence in this area.

The Vivitron started up at just 16.6 MV, and this charge will be progressively increased to 35 MV through next year. The final voltage will be bigger than that of the most powerful existing machines of this type, in particular a 26-MV accelerator at Oak Ridge, Tennessee, in the United States, and a 22-MV in the United Kingdom.

By focusing large but controlled energies on nuclei, Vivitron will cause collisions that produce nuclei with unusual compositions of excited internal states. In particular, it will be used to study 'superdeformation', a phenomenon discovered at Daresbury in 1986.

This is an excited and relatively stable state in which rapidly rotating nuclei deform and acquire an elliptical form. Physicists



say that such nuclei act as a 'laboratory' in which laws governing the structure of the nucleus can be explored in a simplified form.

Usually observed in nuclei of mass around 130, 150 or 190, superdeformation is detected by the emission of specific fingerprints of gamma rays. Identifying these against the noisy background is the job of the FFr60 million Anglo—French detector Eurogam II, which is coupled to Vivitron.

Three other detectors — DEMON, a FFr7 million neutron detector, and ICARE and CHARISSA, both charged particle detectors — will later be coupled to Vivitron. The successor to Eurogam II, which is already the world's highest resolution gamma-ray spectrophotometer, is being planned by France, Britain, Germany, Italy and the Scandinavian countries.

Strasbourg is pitching to host the FFr140 million EUROBALL detector. But the Italian city of Legnaro, near Venice, would also like to host the machine.

Declan Butler