Patent rights

Patient sues for title to own cells

Los Angeles

A FORMER leukaemia patient last week sued doctors at the University of California, Los Angeles (UCLA), for patenting and marketing a cell line derived from his spleen, removed to save his life. The suit, said to be the first of its kind, raises the ethical question of who has the right to profit from biological discoveries made by physicians using patients' organs.

The cell line, named "Mo" after patient John Moore, has potential commercial value in treating or perhaps even curing blood diseases including cancer and acquired immune deficiency syndrome (AIDS), according to Mr Moore and his Beverly Hills attorney, Sanford Gage.

In the lawsuit, filed in Los Angeles Superior Court on 11 September, Mr Moore asserts his ownership of his blood and bodily substances and of any by-products produced from them. The University of California patented the cell line without his permission, he says, but could conceivably make millions of dollars from it.

The UCLA researchers, Dr David W. Golde (chief of haematology and oncology) and medical technician Shirley Quan, say, however, that the cell line has not proved to have any commercial value,

Mr Moore's spleen cells provide an unusually rich source of these proteins, which is why the University of California took out a patent, granted in March 1984, on the line. When the patent was applied for in 1976, there was growing commercial interest in producing interferon as an antiviral agent.

There are now nearly one hundred other cell lines, many of them not patented, which are also rich lymphokine sources. Lymphokines are still defined phenomenologically, and their potential in treating viral diseases is still highly

speculative. But according to Dr Golde and others, Mr Moore's spleen cell line and his blood serum are still especially interesting because of the rarity of his leukaemia and the virus that caused it. **Sandra Blakeslee**

● The question of availability of the Mo T-lymphoblast cell line has caused some controversy. The complexities of the situation were touched upon by Dr Golde (*Nature* 308, 19; 1984), responding to the various requests for the cells. He explains that the cells would become available from the American Type Tissue Culture Collection when UCLA's application for a patent had been processed. Those wanting the B-lymphoblasts from patient Mo, however, are not, it seems, affected by the patent. □

US pharmaceuticals

Patents extended, generics agreed

Washington

A DEFT legislative compromise appears to have pleased both research-based and "generic" pharmaceutical manufacturers in the United States. The two houses of Congress last week agreed on a bill that will extend the lives of patents on new drugs to compensate for the years spent by their manufacturers in seeking regulatory approval. Manufacturers of generic drugs have also won, in that they will in future be able to rely on the original testing data of a drug to back applications to market a generic equivalent once the patent term has expired. The Drug Price Competition and Patent Term Restoration Act, as it will be known, is backed by the administration and is likely to be signed into law within the next few weeks.

The research-based drug companies, represented by the Pharmaceutical Manufacturers Association, have long argued that the lengthy process of obtaining approval for a drug from the Food and Drug Administration (FDA) seriously reduces the incentive to search for new therapeutic compounds. In 1983, according to the association, each new drug brought to the market had soaked up an average of \$91 million in direct and indirect costs, typically over 7 to 10 years. Only one in three drugs provides a reasonable return on this investment, and by the time all regulatory hurdles have been cleared, on average only 9 years of patent life remain out of the total of 17 years.

The new bill will allow an extension of the patent term by up to 5 years, with the proviso that the total remaining patent life after extension cannot exceed 14 years. The extension comprises one half of all the time the company spends testing, plus all the time the FDA spends processing applications. The special needs of genetic engineering companies are recognized in the bill: though normally there can be no more than one patent term extension for each product, substances made by recombinant DNA technology are treated for this

purpose as if they differ from the same substance made by conventional means.

On the other side of the coin, generic brand manufacturers can often sell their products at very much lower prices than the original versions. These manufacturers argue that the public interest is best served by maximizing competition, but they also complain that, as things stand, they are caught in a "paperchase" when seeking regulatory approval for their products. Although, in principle, generic manufacturers may support their applications with data from previous tests on the same substance, the original data are often not published in the open literature, and many tests have to be repeated.

The new act introduces an "abbreviated new drug application" (ANDA) which simply requires the generic manufacturer to show that a product is essentially identical with an existing approved drug in terms of dosage and bioavailability. Senator Orrin Hatch (Republican, Utah), who sponsored the bill, quotes \$1,000 million as the likely savings by consumers over the next 10 years as more generic drugs become available, although more cautious observers say it is impossible to make estimates of this kind.

The wheeling and dealing that went into the bill has led to an unusually complex set of rules on when ANDAs may be filed. An earlier version caused serious divisions within the Pharmaceutical Manufacturers Association because it would have allowed a generic drug manufacturer to obtain approval for a copied drug only 18 months after challenging the validity of a patent covering the product. The result could have been that research-based manufacturers would have had repeatedly to defend themselves against patent challenges. In the final version of the bill, ANDAs linked to patent challenges may be submitted to FDA 4 years after approval of an original drug, though marketing approval for the generic version must wait 7½ years from the original approval. **Tim Beardsley**

even though it is an "enormously valuable research tool". For example, Mo is the cell line which provided the supernatant from which Dr Robert Gallo of the National Cancer Institute isolated a human T-cell lymphotropic virus, called HTLV-II. This virus, which is rare, evidently caused Mr Moore's disease, a T-cell variant of hairy cell leukaemia. A similar virus isolated in 1980 from other cell lines, called HTLV-I, is recognized as the cause of adult T-cell leukaemia, while HTLV-III, discovered in recent months, is the cause of AIDS.

The potential commercial value of the Mo cell line lies in its unusual lymphokine activity. Lymphokines are hormone-like substances secreted by lymphocytes with wide-ranging biological activity. They act locally to modulate cells responsive to them. They include interleukin-2, colony-stimulating factor, neutrophil migration inhibition factor and an erythroid-potentiating protein.