Europe's life patent moratorium may go . . .

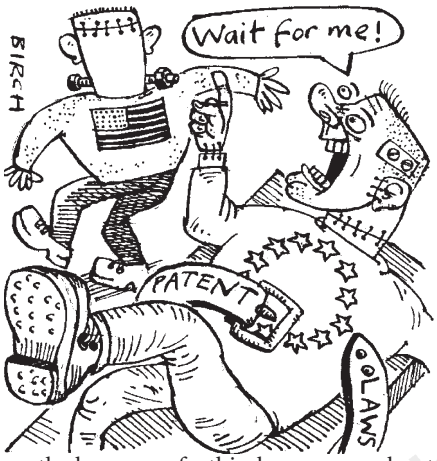
[MUNICH] A moratorium imposed by the European Patent Office (EPO) in 1995 on the patenting of plants and animals is likely to be lifted following last week's approval by the European Parliament of a new European Union (EU) directive on biotechnological inventions.

The directive will also speed up patent procedures because it makes clear what is, and what is not, patentable. But the moratorium may not be lifted for another year.

Officials of the EPO, which is not an EU body, have welcomed the reference point that the directive will provide for its own rules, which were written into its European Patent Convention (EPC) in 1973, before the advent of recombinant DNA technology. These rules, whose interpretation is determined by case law, have proved ambiguous in relation to biotechnological inventions.

According to the new directive, elements of the human body — including partial sequences of genes — are not patentable; nor are procedures for human cloning. But isolated human genes can be patented, provided that their function is known and an application defined, for procedures such as diagnostics.

Transgenic animals or plants are also patentable. Parliament rejected the draft directive the first time round, in March 1995,



partly because of ethical concerns about these issues.

Groups opposed on principle to the patenting of organisms created by genetic engineering routinely challenge all such patent applications, citing a clause in the EPC which states that a patent should not be granted if it is "contrary to public order or morality". EPO boards of appeal have always rejected these challenges.

But opponents have had more luck with a semantic argument relating to another EPC clause, originally intended to protect the rights of plant breeders, which excludes plant and animal varieties from patentability.

This clause was never intended to forbid the patenting of plants and animals in general. But in February 1995, an EPO board of appeal accepted opponents' arguments that the term 'plant' can be considered an umbrella term for a collection of plant varieties — and is thus not patentable under the terms of the convention (see *Nature* **374,** 8; 1995).

Since then, the EPO has issued no patents on animals or plants. Hundreds of applications are therefore pending, awaiting further clarification of the principle.

The EPO hopes that the 1995 precedent will be reversed by its Enlarged Board of Appeals — the EPO's highest legal authority — which has just been asked to interpret the question of plant patentability following a challenge to a Novartis patent on a plant genetically engineered to be herbicide-resistant.

EPO officials decline to anticipate the outcome of the Enlarged Board of Appeals. But the board is now almost certain to take the new directive as its guidance, particularly as its formal request for clarification was delayed until after the parliamentary vote.

In the unlikely event that it rejects the directive as guidance, then, says Christian Guggerell, an EPO expert on biotechnological inventions, the 18 signatories of the EPO will have to agree to rewrite the EPC rules, a process that could take many years.

Simon Cohen, a London-based patent lawyer with the firm of Taylor Joynson Garrett, says that, as the directive makes clear that human genes with a described function and application as well as transgenic animals and plants are patentable, there will be fewer oppositions to patents on biotechnological inventions. "This will speed up patenting procedures for biotechnology companies."

He points out, however, that there will still be plenty of room for challenges based on ethical considerations, as the directive excludes from patentability "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal".

Brian Yorke, head of corporate intellectual property at Novartis, agrees that the "clarity and balance" of the patent directive will make life much easier for industry. He believes that the Novartis case being considered by the EPO Enlarged Board of Appeal can — and probably will — be interpreted "as being in line with the EU patent directive". Otherwise, he says, the EPO would be out of line with future national legislation in EU countries, all of which are EPO member states.

The directive on biotechnological inventions, whose formal approval is assured, must be incorporated into national law within two years by all EU member states. **Alison Abbott**

... as US office claims right to rule on morality

[WASHINGTON] The US patent office is claiming it has the authority to stop the issuing of a patent, on moral grounds alone, for ways to make human–animal chimaeras (see *Nature* **392,** 423, 1998). The office is currently faced with a broad-ranging application for such a patent.

But the applicants – Jeremy Rifkin, the president of the Foundation on Economic Trends, a Washington advocacy group, and Stuart Newman, a developmental biologist at New York Medical College in Valhalla, New York – say that there is no legal basis for such an assertion.

Even if there was such a basis, they say, it would be impossible for the Patent and Trademark Office (PTO) to draw a line defining what is and what is not morally acceptable.

Rifkin and Newman filed for a patent last December on methods for creating a 'human/animal chimaera', and say that their intention is to raise a broad public and legal debate about the implications of such a patent.

On the same day (2 April) that news first broke of the application, Bruce Lehman, the PTO commissioner, issued a statement asserting that the PTO's legal authority allows it to deny patents deemed to be "injurious to the well-being, good policy or good morals of society".

Lehman's statement said it was the position of the PTO that inventions directed to human/non-human chimaeras could not be patentable "because, among other things, they would fail to meet the public policy and morality aspects" of patent law". Lehman says that this position is based on a court decision of 1817.

Lehman also argued that Rifkin and Newman are engaged in an attempt "to panic people into an overreaction". But the two applicants say that their application is based on perfectly feasible technology, and that patent law gives Lehman no 'moral' grounds for blocking an application.

Even if it did, they say, it would be impossible for the PTO to draw a line between 'moral' human–animal mixes and 'monsters'. Newman asks: what would rationally distinguish their creation from inventions that have already been applied for, such as pigs carrying human genes as sources of transplantable organs?

Rifkin has already said that he would mount a legal challenge to any rejection of his application by the patent office. **Meredith Wadman**