Time to abandon Brussels' bid on patents

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After six years of debate, the European Commission's attempts to harmonize biotechnology legislation still face opposition over the patenting of genes. Recent legal experience suggests that its efforts are unnecessary.

NEXT week, a critical meeting takes place in Brussels which could well determine the fate of the European commission's six-year attempt to harmonize legislation on biotechnology patents among the 12 — soon to be expanded — members of the European Union (EU).

The meeting is of the conciliation committee, a body established under the Maastricht Treaty in order to resolve differences between the European Parliament and the Council of Ministers. The main difference to be resolved in this instance relates to the extent to which individual genes can be patented. As such, it goes to the heart of the future of the biotechnology industry.

Article 2 of the draft directive specifies three particular categories of inventions which are unpatentable: the human body or "parts of the human body as such"; processes for modifying the genetic identity of the human body "contrary to the dignity of man"; and processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps "without any substantial benefit to man or animal", and animals resulting from such processes.

The phrase "parts of the human body as such" is intended to mean parts of the human body as they are found inside the body. According to language elsewhere in the directive, this reaffirms the general principle that no-one should, by obtaining a patent, be able to claim ownership of, for example, a gene, protein or cell in its natural state in the human body.

In May, however, the European Parliament passed a proposed amendment to this section which would also bar patents on genes, proteins or cells that have been isolated from the body. The Parliament wants an explicit and unambiguous statement that no part of the human body can be patented — whether or not it has been isolated. In addition, it has proposed an absolute ban on patenting human genes and gene therapies.

The European Parliament is apparently concerned that the term 'as such' may be ambiguous, and might permit the type of patent application for gene sequences made (but subsequently withdrawn) by both the US National Institutes of Health and Britain's Medical Research Council for sequences of genes whose functions had not been determined.

But the effect of the proposed amendment would be devastating. In particular, it would preclude patents on many types of therapeutic proteins which have only become available as a result of the efforts of scientists who have successfully cloned the relevant gene and expressed the protein in a suitable host.

If approved, the Parliament's proposal could cause major damage to the biotechnology industry. For it would remove the incentive to the pharmaceutical companies which support these scientists to continue to back their search for effective therapeutic treatments for the many gene-based illnesses. Indeed, the Parliament's recommendation raises the question of whether we need the directive at all. We would argue that we do not.

Current patent law across Europe conforms with the European Patent Convention (EPC), a pan-European agreement drawn up in 1973 and now signed by all member states of the European Union (in their individual capacities) as well as some non-EU countries (Austria, Sweden and Switzerland).

Inventors wishing patent protection in EPC countries can either apply to the European Patent Office (EPO) in Munich, designating the individual signatory states in which they want the patent protected, or make individual applications to national patent offices. The EPO route is usually preferred, as it involves a single application covering many states.

Many challenges have already been made to biotechnology patents which have led to hearings before the EPO's Opposition Division and Board of Appeal. In addition, both the EPO and national courts have handed down numerous judgments dealing with such patents.

Neither has felt the need for new legislation to deal with issues raised by genetic engineering, even though the technology has progressed enormously since the EPC was drawn up. This is primarily because the convention provides an adequate framework for courts to apply existing patent law to a particular case.

For an invention to be patentable, various hurdles need to be overcome. One is that it must involve an inventive step. The EPO usually evaluates this by deciding whether an invention solves a technical problem in the field. In addition, the invention must also be industrially applicable. And the patent must not be "contrary to *'ordre public'* or morality".

All three requirements already give patent offices and the courts the scope either to refuse applications, or to revoke patents such as those relating to gene sequences with no determined functions (as in the NIH applications), should they choose to do so.

The new directive, in the form now proposed by the commission, is not significantly different from the existing law as promulgated by the European Patent Offices and the national courts. As all EU member states are signatories to the EPC, it can be argued the laws of those states on this issue are already harmonized.

All the commission's efforts appear to have done is to provide a platform for lobby groups to mount a fierce attack on the whole principle of patenting the results of genetic research. If changes are required in the future, this could be done through an amendment to the EPC. There would be no need for the commission to get involved.

Moreover, European patent law is dynamic, constantly evolving to deal with new issues and developing technologies. Last month, for example, Britain's Court of Appeal set a controversial precedent when it handed down a judgment on a challenge from Medeva plc to Biogen Inc.'s patent on a hepatitis B vaccine produced by recombinant DNA technology.

Although the Appeal Court found against Biogen, its decision is widely seen as being out of line with established European patent law, and Biogen is likely to attempt to appeal the decision to the House of Lords. But whatever the outcome, no-one is suggesting that new legislation is required. The argument is over the interpretation of existing legislation.

It is far better to give courts the scope to rule on the desirability of biotechnology patents in this area under the existing provisions, rather than seek to place them in a straightjacket, with little room for manoeuvre.

The biotechnology directive in its current form is certainly unhelpful. Even more importantly, the directive is not needed. It should be shelved without further ado. □

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