



International Chamber of Commerce

The world business organization

Policy statement

Biotechnology patents in the European Union

Prepared by the Commission on Intellectual and Industrial Property

ICC comments on the amended proposal for the European Parliament and Council directive on the legal protection of biotechnological inventions.

The ICC is the world business organization. As such, it has always supported strong intellectual property rights and the principle of non-discrimination in the protection of intellectual property, whether with respect to geographical origin or type of invention in the case of patents. Companies from all over the world doing business in the European Union, including many European companies, are active in and through the ICC; in the following comments they express their views from a global perspective. A global technology of enormous power, it is important that biotechnology should be regulated in all countries in the same overall spirit, though some adaptation to local needs may be both necessary and appropriate.

The ICC thus supports the European Union's efforts towards putting in place a system to allow the protection of biotechnological inventions through patents, and applauds the progress made with the European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions. Getting the approval of the European Parliament on the European Commission's amended proposal on First Reading by a majority of over three to one, in a most satisfactory form, is a considerable success. The ICC further welcomes the latest changes proposed by the European Commission.

Of course, this latest proposal is not perfect – the ICC makes some criticisms below. However, in the present circumstances the ICC would warn against further substantial amendment, except where clearly an improvement. Most of the current text has become familiar over time, and its implications are understood. The ICC is concerned that a significant last-minute amendment may be introduced that could have serious effects that are not immediately appreciated. The ICC would plead for the greatest possible care in further amendment to the document.

Specific comments

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The ICC has a number of more specific comments, set out below. Except where otherwise mentioned, references are to Articles and Recitals as renumbered by the European Commission in its amended proposal (Coma(97) 446 Final).

Ethics

The ICC accepts the changes that have been made in **Article 6** by the European Parliament and Commission. In particular, the change in Article 6(d) is welcome as limiting the balancing of incommensurables (animal pain against human benefit), the approach currently favoured by the European Patent Office (EPO). The limitation of benefit to “medical” is disturbing, since this may not allow alleviation of human hunger. The ICC thinks it should allow this. Few citizens of the European Union go hungry, but hunger is a major issue for the global community. The EU cannot isolate itself from this global perspective, but has the responsibility to create a framework in which researchers and industry can contribute to solving the problems of world hunger using the tools of biotechnology.

Article 7 provides a good way of meeting the ethical concerns that have been expressed, by allowing patenting problems, should any arise, to take their place in context with other problems in the area.

A small concern is the wording of **Recital 22**. It is unacceptable to produce beings which are chimeras of human and animal genomes, or totipotent cells capable of developing into such beings. The ICC sees no objection, however, to fusing two differentiated cells, as in the production of monoclonal antibodies. These have proved very useful in human medicine, and have not (so far as the ICC knows) caused any ethical concern.

Patenting of natural elements

The new **Article 5** (with its corresponding **Recitals 16-16(g)**) is crucial to the whole Directive. The scheme of balancing what is unpatentable (in Article 5.1) against what remains patentable (in Article 5.2) is an excellent one, and offers the best chance of making this highly contentious area absolutely clear. Perhaps to talk of ‘genes’ is too limiting: functional parts of genes, such as tissue-specific promoters, and similar elements, also justify protection. Apart from some small amendment to make this clearer, the ICC strongly suggests that Article 5 should **not** be changed.

There are however problems with **Recital 16d**. The first part of it suggests that all functional nucleic acid sequences code for proteins. This is not so. As to the second part, the ICC does not understand which problem it is proposing to remedy. The ICC fears national legislators will not understand either, resulting in inconsistency and confusion. The ICC suggests that the recital be deleted.

Multiplication of Patented Biological Material

Article 8.1 embodies one of the main benefits of the Directive, in making clear that

unauthorized multiplication is infringement. It is vital that this Article should be maintained in essentially its present form.

Source of Patented Biological Materials

The ICC is pleased to see that the European Commission has deleted **Article 8A**, regarding the origins of biological materials, which had been proposed by the Parliament. While the ICC understands the motives for these proposals, implementing them would put a significant burden on patent applicants and patent examiners, and prevent patenting of some worthwhile inventions. They go beyond what is required under the Biodiversity Convention, and are inconsistent with TRIPS. There are also problems with data protection laws, where materials obtained from humans are involved. The objectives sought should be met in some other way.

Patenting of plants and animals - exclusion of ‘varieties’

Article 4.2 and **Recitals 17-17b** deal with this important question. The ICC has two comments.

Firstly, “a plant totality” (**Recital 17b**) would normally be understood (at least in English) to mean “a whole plant”. It would be better to refer to “a plant grouping”, the phrase used in UPOV 1991 and in the corresponding Regulation. If that term is being deliberately avoided, this is a mistake. The whole point is that a plant variety is a very specific kind of plant grouping, and that other kinds of plant grouping should be eligible for patenting. Secondly, given the enormous difficulty that the European Patent Office has found in deciding when to allow patent protection for plants, the ICC thinks it would be worth redrafting Recitals 17a and 17b to emphasise even further the reason for (and hence the limits of) the exclusion of plant varieties. The ICC suggests the following:

“(17a) Whereas the concept ‘plant variety’ is defined by the law protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality; whereas it is clearly distinguishable from other varieties *and may (when new) be protected under Regulation (EC) No 2100/94 and similar plant variety protection laws;*”

“(17b) Whereas a *new plant grouping* which is characterised by a particular gene (and not its whole genome) *is a generic innovation, not a plant variety, and cannot be protected under plant variety protection laws; whereas such an innovation may be deserving of protection and therefore should be eligible for patent protection and* not excluded from patentability even if it comprises plant varieties;” [added words in italics]

International Conventions

The ICC welcomes the emphasis placed in the new **Recitals 34 and 37** on both TRIPS and the Biodiversity Convention. It is valuable to make clear that these both form part of Community law. While the interrelationship between these two instruments has yet to be fully worked out, in our view, if they are properly interpreted, there is no conflict in their fundamental aims.



TRIPS is a treaty of fundamental importance to the global business community and to the rapid and orderly development of innovation throughout the world. The ICC believes that intellectual property rights, as promoted by TRIPS, have important contributions to make to the aims of the Biodiversity Convention. It is useful also that new **Recital 19c** makes it clear that no invention can be refused protection as immoral if its commercial exploitation is legal.

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