NETHERLANDS v PARLIAMENT AND COUNCIL

JUDGMENT OF THE COURT 9 October 2001

In Case C-377/98,

Keywords

1. Approximation of laws - Legal protection of biotechnological inventions - Directive 98/44 - Legal basis - Article 100a of the Treaty (now, after amendment, Article 95 EC)

(EC Treaty, Art. 100a (now, after amendment, Art. 95 EC) and Arts 130 and 130f (now Arts 157 EC and 163 EC); European Parliament and Council Directive 98/44)

2. Approximation of laws - Legal protection of biotechnological inventions - Directive 98/44 - Inventions whose commercial exploitation would be contrary to ordre public or morality - Not patentable - Scope allowed to Member States in applying criterion for exclusion - Not discretionary

(European Parliament and Council Directive 98/44, Art. 6)

3. Approximation of laws - Legal protection of biotechnological inventions - Directive 98/44 - Patentability of plant varieties - Whether permissible - Conditions

(European Parliament and Council Directive 98/44, Art. 4)

4. Approximation of laws - Legal protection of biotechnological inventions - Directive 98/44 - Protection conferred by the patent - Scope

(European Parliament and Council Directive 98/44, Arts 8 and 9)

5. Actions for annulment - Pleas in law - Breach of international obligations - Possibility of relying on the Rio de Janeiro Convention on Biological Diversity of 5 June 1992 to contest the lawfulness of a Community measure - Conditions

(EC Treaty, Art. 173 (now, after amendment, Art. 230 EC))

6. Community law - Principles - Fundamental rights - Observance ensured by the Community judicature - Legal protection of biotechnological inventions - Directive 98/44 - Patentability of inventions which combine a natural element

with a technical process enabling it to be isolated or produced for an industrial application - Right to human dignity - Breach - None

(European Parliament and Council Directive 98/44, Art. 5(1), (3) and (6))

7. Acts of the institutions - Statement of reasons - Obligation - Scope

(EC Treaty, Art. 190 (now Art. 253 EC))

Summary

1. The legal basis on which an act must be adopted should be determined according to its main object. Whilst it is common ground, in that regard, that the aim of Directive 98/44 on the legal protection of biotechnological inventions is to promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in national legislation and case-law and are likely to impede and disrupt research and development activity in that field. Approximation of the legislation of the Member States is therefore not an incidental or subsidiary objective of the Directive but is its essential purpose. The fact that it also pursues an objective falling within Articles 130 and 130f of the Treaty (now Articles 157 and 163 EC) is not, therefore, such as to make it inappropriate to use Article 100a of the Treaty (now, after amendment, Article 95 EC) as the legal basis of the Directive.

(see paras 27-28)

2. Article 6 of Directive 98/44 on the legal protection of biotechnological inventions, which rules out the patentability of inventions whose commercial exploitation would be contrary to ordre public or morality, allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion. However, that scope for manoeuvre is not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to ordre public or morality merely because it is prohibited by law or regulation, and by giving four examples of processes or uses which are not patentable.

(see paras 37, 39)

3. It is clear inter alia from Article 4 of Directive 98/44 on the legal protection of biotechnological inventions, according to which a patent may not be granted for a plant variety but may be for an invention if its technical feasibility is not confined to a particular plant variety, that a genetic modification of a specific plant variety is not patentable but a modification of wider scope, concerning, for example, a species, may be.

(see paras 43-45)

4. Articles 8 and 9 of Directive 98/44 on the legal protection of biotechnological inventions, according to which the protection conferred by the patent extends to any biological material derived through propagation or multiplication from the biological material containing the patented information, do not concern the principle of patentability but the scope of that protection. That protection may therefore cover a plant variety, without that variety being patentable in itself.

(see para. 46)

5. As a rule, the lawfulness of a Community instrument does not depend on its conformity with an international agreement to which the Community is not a party, such as the Munich Convention on the Grant of European Patents of 5 October 1973. Nor can its lawfulness be assessed in the light of instruments of international law which, like the Agreement establishing the World Trade Organisation and the Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and on Technical Barriers to Trade which are part of it, are not in principle, having regard to their nature and structure, among the rules in the light of which the Court is to review the lawfulness of measures adopted by the Community institutions.

However, such an exclusion cannot be applied to the Rio de Janeiro Convention on Biological Diversity of 5 June 1992 which, unlike the Agreement establishing the World Trade Agreement, is not strictly based on reciprocal and mutually advantageous arrangements. Even if that convention contains provisions which do not have direct effect, in the sense that they do not create rights which individuals can rely on directly before the courts, that fact does not preclude review by the courts of compliance with the obligations incumbent on the Community as a party to that agreement.

(see paras 52-54)

6. It is for the Court of Justice, in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed. As regards living matter of human origin, Directive 98/44 on the legal protection of biotechnological inventions frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.

First, Article 5(1) of the Directive provides that the human body at the various stages of its formation and development cannot constitute a patentable invention.

Second, the elements of the human body are not patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent. Thus, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated. That distinction applies to work on the sequence or partial sequence of human genes. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by Article 5(3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the discovery of a DNA sequence, which would not be patentable as such. Thus, the protection envisaged by the Directive covers only the result of inventive, scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application.

Moreover, reliance on the right to human integrity, which encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient is misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products.

(see paras 70-75, 77-79)

7. The obligation to state reasons for directives under Article 190 of the EC Treaty (now Article 253 EC) does not extend to a requirement that the signatures on proposals and opinions mentioned in that article must include a summary of the facts to establish that each of the institutions involved in the legislative procedure observed its procedural rules.

Furthermore, it is only where there is serious doubt as to whether the procedure prior to its intervention was followed properly that an institution is justified in investigating the matter.

(see paras 86-87)