Judgment of the Court of Justice, Netherlands v Parliament and Council, Case C-377/98 (9 October 2001)

Caption: In its judgment of 9 October 2001, in Case C-377/98, Netherlands v Parliament and Council, in response to the application for annulment of the directive on the legal protection of biotechnological inventions, the Court of Justice rejects the second plea (breach of the principle of subsidiarity), since the objective pursued by the directive could not be achieved by action taken by the Member States alone and, given the scale and effects of the proposed action, could be better achieved at Community level.

Source: CVRIA. Case-law: Numerical access to the case-law. [ON-LINE]. [Luxembourg]: Court of Justice of the European Communities, [12.05.2006]. C-377/98. Available on http://curia.eu.int/en/content/juris/index.htm.

URL:
http://www.cvce.eu/obj/judgment_of_the_court_of_justice_netherlands_v_parliament_and_council_case_c_377_98_9_october_2001-en-200fcb6b-a916-4467-880f-af2c3643cb57.html

Publication date: 06/09/2012

Judgment of the Court of 9 October 2001 (1)
Kingdom of the Netherlands v European Parliament and Council of the European Union

Case C-377/98

(Annulment - Directive 98/44/EC - Legal protection of biotechnological inventions - Legal basis - Article 100a of the EC Treaty (now, after amendment, Article 95 EC), Article 235 of the EC Treaty (now Article 308 EC) or Articles 130 and 130f of the EC Treaty (now Articles 157 EC and 163 EC) - Subsidiarity - Legal certainty - Obligations of Member States under international law - Fundamental rights - Human dignity - Principle of collegiality for draft legislation of the Commission)

In Case C-377/98,

Kingdom of the Netherlands, represented by M.A. Fierstra and I. van der Steen, acting as Agents,

applicant,

supported by

Italian Republic, represented by U. Leanza, acting as Agent, assisted by P.G. Ferri, avvocato dello Stato, with an address for service in Luxembourg,

and by

Kingdom of Norway, represented by H.W. Longva, acting as Agent,

interveners,

v

European Parliament, represented by J. Schoo and E. Vandenbosch, acting as Agents, with an address for service in Luxembourg,

and

Council of the European Union, represented by R. Gosalbo Bono, G. Houttuin and A. Lo Monaco, acting as Agents, with an address for service in Luxembourg,

defendants,

supported by

Commission of the European Communities, represented by K. Banks and P. van Nuffel, acting as Agents, with an address for service in Luxembourg,

intervener,

APPLICATION for annulment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann, F. Macken, N. Colneric and S. von Bahr

(Presidents of Chambers), C. Gulmann, D.A.O. Edward, A. La Pergola, J.-P. Puissochet (Rapporteur), L. Sevón, M. Wathelet, V. Skouris and J.N. Cunha Rodrigues, Judges,

Advocate General: F.G. Jacobs,

Registrar: H.A. Rühl, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 13 February 2001, at which the Kingdom of the Netherlands was represented by J. van Bakel, acting as Agent, the Italian Republic by D. Del Gaizo, avvocato dello Stato, the Kingdom of Norway by H. Seland, acting as Agent, the European Parliament by J. Schoo and E. Vandenbosch, the Council by G. Houttuin and A. Lo Monaco and the Commission by K. Banks and P. van Nuffel,

after hearing the Opinion of the Advocate General at the sitting on 14 June 2001,

gives the following

Judgment

1. By application lodged at the Court Registry on 19 October 1998, the Kingdom of the Netherlands brought an action under Article 173 of the EC Treaty (now, after amendment, Article 230 EC) for annulment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13, hereinafter the Directive).

2. The Directive was adopted on the basis of Article 100a of the EC Treaty (now, after amendment, Article 95 EC), and its purpose is to require the Member States, through their patent laws, to protect biotechnological inventions, whilst complying with their international obligations.

3. To that end the Directive determines inter alia which inventions involving plants, animals or the human body may or may not be patented.

4. The applicant states, as a preliminary point, that it is acting at the express request of the Netherlands Parliament, in the light of the opposition expressed there to genetic manipulation involving animals and plants and to the issuing of patents for the products of biotechnological procedures liable to promote such manipulation.

5. By order of the President of the Court of 28 April 1999, the Commission of the European Communities was granted leave to intervene in support of the forms of order sought by the European Parliament and the Council of the European Union. By orders of the President of the Court of 3 May 1999 the Italian Republic and the Kingdom of Norway were granted leave to intervene in support of the forms of order sought by the Kingdom of the Netherlands.

Admissibility of intervention by the Kingdom of Norway

6. The Parliament and the Council submit that the statement lodged on 19 March 1999 by the Kingdom of Norway merely draws the attention of the Court to certain problems which the implementation of the Directive might pose in connection with the Agreement on the European Economic Area (hereinafter the EEA Agreement), without itself seeking the form of order sought in the application or seeking annulment of the Directive. Consequently, it does not constitute an intervention in support of the forms of order sought by the Kingdom of the Netherlands and is therefore not admissible.

7. In that regard, Article 37 of the EC Statute of the Court of Justice provides that applications to intervene are to be limited to supporting the form of order sought by one of the parties.

8. As it states in its conclusion, the statement lodged by the Norwegian Government seeks to make the point that [s]everal of the questions presented by the Netherlands Government in its action for annulment of Directive 98/44 may have a bearing on whether or not the Directive falls within the EEA Agreement and on the implementation of the Directive into the EEA Agreement, and to request the Court to take due account of the arguments set out by the Norwegian Government in that connection.

9. Although, read literally, the objective so described appears different from that which a statement in intervention can legitimately pursue, it is clear that the intention of the Norwegian Government was not to seek further forms of order in addition to those sought by the applicant nor to ask the Court to rule on separate issues, but to contribute to the success of the action of the Netherlands Government by shedding further light on the dispute.

10. That analysis is confirmed by the fact that all the arguments contained in the Norwegian Government's statement reiterate, and on some points develop, the views stated in the application of the Kingdom of the Netherlands.

11. The statement lodged by the Kingdom of Norway taken overall and in its context, must therefore be held to be admissible as a statement in intervention in support of the forms of order sought by the applicant.

The pleas relied on in the application

12. The applicant puts forward six pleas: that Article 100a of the Treaty was the incorrect legal basis for the Directive, breach of the principle of subsidiarity, breach of the principle of legal certainty, breach of obligations in international law, breach of the fundamental right to respect for human dignity and breach of procedural rules in the adoption of the Commission's proposal.

The first plea

13. The applicant submits that the Directive does not fall within the definition of measures for approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market, and was incorrectly adopted on the basis of Article 100a of the Treaty.

14. In the first place, the differences in the laws and practices of the Member States and the likelihood of their becoming greater, to which the fifth and sixth recitals of the preamble to the Directive allude, stating that they could create barriers to trade, do not exist or only concern secondary issues which do not justify harmonisation.

15. In that regard, it must be borne in mind that recourse to Article 100a as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws provided that the emergence of such obstacles is likely and the measure in question is designed to prevent them (Case C-350/92 Spain v Council [1995] ECR I-1985, paragraph 35, and Case C-376/98 Germany v Parliament and Council [2000] ECR I-8419, paragraph 86).

16. The examples given by the Parliament and the Council suffice to establish that, even if the relevant national provisions predating the Directive are most often taken from the Convention on the Grant of European Patents, signed at Munich on 5 October 1973, (hereinafter the EPC), the differing interpretations to which those provisions are open as regards the patentability of biotechnological inventions are liable to give rise to divergences of practice and case-law prejudicial to the proper operation of the internal market.

17. Moreover, in addition to the risk of divergent trends, at the time the Directive was adopted marked differences with significant consequences were already apparent between certain national laws on specific points such as the patentability of plant varieties and that of the human body,

18. By requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive in fact aims to prevent damage to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection.

19. However, the applicant submits, secondly, that if the application by the Member States of the relevant provisions of international law left a measure of legal uncertainty, it should have been removed not by Community harmonisation but by renegotiation of international legal instruments such as the EPC, in order to clarify their rules.

20. That argument is unfounded. The purpose of harmonisation is to reduce the obstacles, whatever their origin, to the operation of the internal market which differences between the situations in the Member States represent. If divergences are the result of an interpretation which is contrary, or may prove contrary, to the terms of international legal instruments to which the Member States are parties, there is nothing in principle to prevent recourse to adoption of a Directive as a means of ensuring a uniform interpretation of such terms by the Member States.

21. Moreover, it does not appear, in the present case, that such an approach is inconsistent with the Member States' honouring their obligations under the EPC or is unsuitable for achieving the objective of creating uniform conditions for the patentability of biotechnological inventions.

22. Accordingly, there was nothing to prevent the Community legislature from having recourse to harmonisation by means of a directive in preference to the more indirect and unpredictable approach of seeking to amend the wording of the EPC.

23. Thirdly, according to the applicant, the Directive goes beyond what ought to fall within the definition of a measure for approximation of the legislation of the Member States, given that, in fact, it creates a new type of property right distinct in several respects from the rights covered by existing patent law. In particular, apart from the fact that it concerns products previously excluded from patentability in certain Member States such as the Kingdom of the Netherlands, the Directive is different from existing patent law in that, by virtue of Articles 8 and 9, the protection it provides for applies not only to specific biological material but also to biological material obtained from it by reproduction or multiplication, and that under Article 11 the right of the holder of the patent, as against farmers, is limited.

24. As the Court has already stated at point 59 of Opinion 1/94 of 15 November 1994 ([1994] ECR I-5267), the Community is competent, in the field of intellectual property, to harmonise national laws pursuant to Article 100 of the EC Treaty (now Article 94 EC) and Article 100a of the Treaty and may use Article 235 of the EC Treaty (now Article 308 EC) as the basis for creating new rights superimposed on national rights, as it did in Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ 1994 L 11, p. 1).

25. The patents to be issued under the Directive are national patents, issued in accordance with the procedures applicable in the Member States and deriving their protective force from national law. As the creation of a Community patent is neither the purpose nor the effect of the Directive, it does not introduce a new right which would require recourse to the legal basis afforded by Article 235 of the Treaty. That view is not affected by the fact that the inventions covered were not previously patentable in certain Member States - that, indeed, is precisely why harmonisation was warranted - nor by the fact that the Directive makes certain clarifications and provides for derogations from patent law as regards the scope of the protection.

26. Fourthly, and finally, the Italian Government takes the view, in its intervention in support of the applicant, that the Directive should have been adopted on the basis of Articles 130 and 130f of the EC Treaty (now Articles 157 EC and 163 EC), and not Article 100a of the Treaty since the chief aim of the Directive, as the first three recitals of the preamble show, is to support the industrial development of the Community and scientific research in the genetic engineering sector.

27. The legal basis on which an act must be adopted should be determined according to its main object (see

Case C-155/91 Commission v Council [1993] ECR I-939, paragraphs 19 to 21). Whilst it is common ground, in that regard, that the aim of the Directive 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.

28. 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 is not, therefore, such as to make it inappropriate to use Article 100a of the Treaty as the legal basis of the Directive (see, by analogy, Case C-62/88 Greece v Council [1990] ECR I-1527, paragraphs 18 to 20).

29. It follows that the Directive was correctly adopted on the basis of Article 100a of the Treaty and that the first plea must, therefore, be rejected.

The second plea

30. The applicant submits that the Directive breaches the principle of subsidiarity laid down by Article 3b of the EC Treaty (now Article 5 EC) and, in the alternative, that it does not state sufficient reasons to establish that this requirement was taken into account.

31. It should be borne in mind that, under the second paragraph of Article 3b of the EC Treaty, in areas which do not fall within its exclusive competence, the Community is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

32. The objective pursued by the Directive, to ensure smooth operation of the internal market by preventing or eliminating differences between the legislation and practice of the various Member States in the area of the protection of biotechnological inventions, could not be achieved by action taken by the Member States alone. As the scope of that protection has immediate effects on trade, and, accordingly, on intra-Community trade, it is clear that, given the scale and effects of the proposed action, the objective in question could be better achieved by the Community.

33. Compliance with the principle of subsidiarity is necessarily implicit in the fifth, sixth and seventh recitals of the preamble to the Directive, which state that, in the absence of action at Community level, the development of the laws and practices of the different Member States impedes the proper functioning of the internal market. It thus appears that the Directive states sufficient reasons on that point.

34. The second plea in law must, therefore, be rejected.

The third plea in law

35. The applicant submits that, rather than helping to remove the legal ambiguities described in the recitals, the Directive tends to exacerbate them, thus breaching the principle of legal certainty. First, it gives the national authorities a discretion in applying concepts expressed in general and ambiguous terms, such as ordre public and morality which appear in Article 6. Second, there are unclear provisions whose relationship with one another is ambiguous existing side by side in the Directive, particularly as regards the patentability of plant varieties, mentioned in Article 4(1) and (2), in Articles 8 and 9, and in the 31st and 32nd recitals of the preamble to the Directive.

36. The two specific grounds relied on by the applicant in support of its submission of breach of legal certainty should be examined separately.

37. As regards, first, Article 6 of the Directive, which rules out the patentability of inventions whose commercial exploitation would be contrary to ordre public or morality, it is common ground that this

provision allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion.

38. However, that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities. That sort of provision, which allows patents to be refused where there is a threat to ordre public or morality is, moreover, a well known one in patent law and appears inter alia in the relevant international legal instruments, such as the EPC.

39. Furthermore, the scope for manoeuvre left to Member States 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. Thus, the Community legislature gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents.

40. Finally, a directive cannot be considered contrary to the principle of legal certainty if it relies, as regards the conditions for its implementation, on concepts known to the laws of the Member States, specifying, as here, their scope and limits and taking account, in order to do so, of the specific nature of the subject-matter.

41. Article 6 of the Directive is not therefore such as to exacerbate the legal uncertainty which the Directive seeks to alleviate.

42. Second, as regards the patentability of plant varieties, examination of the provisions mentioned in the application reveals no inconsistency.

43. As the Parliament and the Council explained in their defence, Article 4 of the Directive provides that 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.
44. That distinction is made clear by the 29th to 32nd recitals of the preamble to the Directive, which indicate that plant varieties as such are covered by the legislation on protection of new plant varieties, but that the protection of new varieties applies only to varieties which are defined by their whole genome. For plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, there is no risk of conflict between the legislation on new varieties and the legislation on patents. Thus, inventions which incorporate only one gene and concern a grouping wider than a single plant variety may be patented.

45. It follows 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.

46. Articles 8 and 9 of the Directive do not concern the principle of patentability but the scope of the protection conferred by the patent. According to those provisions, the protection extends to any biological material derived through propagation or multiplication from the biological material containing the patented information. The protection conferred by the patent may therefore cover a plant variety, without that variety being patentable in itself.

47. Finally, Article 12 covers, through a system of compulsory licences, cases where the exploitation of a patent issued for a biotechnological invention would infringe a prior plant patent, and vice versa.

48. Therefore, the two grounds relied on by the applicant to support its plea that the Directive gives rise to legal uncertainty do not justify its annulment.

49. The third plea must, therefore, be rejected.

The fourth plea

50. The applicant submits that the obligations created by the Directive for Member States are incompatible with those resulting from their international undertakings, even though, according to Article 1(2) of the Directive, it does not affect obligations under international agreements. In particular, the Directive breaches the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPs), as set out in Annex 1 C to the Agreement establishing the World Trade Organisation (hereinafter the WTO Agreement), approved on behalf of the European Community, as regards matters within its competence, by Council Decision 94/800/EC of 22 December 1994 (OJ 1994 L 336, p. 1), the Agreement on Technical Barriers to Trade (hereinafter the TBT Agreement), the EPC and the Convention on Biological Diversity signed on 5 June 1992 in Rio de Janeiro (hereinafter the CBD), approved by the European Community by Council Decision 93/626/EEC of 25 October 1993 (OJ 1993 L 309, p. 1).

51. As their main argument, the Parliament and Council submit that the EPC does not create obligations for the Community, which is not a party to it. As regards the other three international legal instruments cited, the Council submits that the legality of a Community instrument can be called in question on grounds of breach of international agreements to which the Community is a party only if the provisions of those agreements have direct effect. That is not so in the present case.

52. It is common ground that, 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 EPC. Nor can its lawfulness be assessed in the light of instruments of international law which, like the WTO agreement and the TRIPS and TBT agreements 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 (Case C-149/96 Portugal v Council [1999] ECR I-8395, paragraph 47).

53. However, such an exclusion cannot be applied to the CBD, which, unlike the WTO agreement, is not strictly based on reciprocal and mutually advantageous arrangements (see Portugal v Council, cited above, paragraphs 42 to 46).

54. Even if, as the Council maintains, the CBD 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 (Case C-162/96 Racke [1998] ECR I-3655, paragraphs 45, 47 and 51).

55. Moreover, and in any event, this plea should be understood as being directed, not so much at a direct breach by the Community of its international obligations, as at an obligation imposed on the Member States by the Directive to breach their own obligations under international law, while the Directive itself claims not to affect those obligations.

56. For that reason at least, the plea is admissible.

57. The applicant argues essentially, first, that Article 27(3)(b) of the TRIPS Agreement allows Member States not to grant a patent for plants and animals other than micro-organisms, whereas the Directive does not allow Member States that possibility.

58. In that regard, suffice it to note that, while the Directive does deprive the Member States of the choice which the TRIPS Agreement offers the parties to that agreement as regards the patentability of plants and animals, the option taken in Article 4 of the Directive is in itself compatible with the Agreement, which, moreover, does not prevent certain party States adopting a common position with a view to its application. The joint selection of an option offered by an international instrument to which the Member States are parties is an act that falls within the approximation of laws provided for by Article 100a of the Treaty.

59. Second, it is claimed that the Directive contains technical regulations within the meaning of the TBT Agreement which should have been notified to the secretariat of the World Trade Organisation.

60. It is, however, established that the Directive does not in any event contain any technical regulations within the meaning of the TBT Agreement, such a regulation being defined in Annex I to the WTO Agreement as a document which lays down product characteristics or their related processes and production methods. It is therefore not necessary to rule on the extent to which the legal protection of biotechnological inventions might fall within the scope of the TBT Agreement.

61. The applicant submits, thirdly, that Article 6(1) of the Directive, which rules out the patentability of inventions whose commercial exploitation would be contrary to ordre public or morality, is incompatible with Article 53 of the EPC, which excludes from patentability inventions the publication or exploitation of which would be contrary to ordre public or morality. The difference in the terms used, it is argued, has an effect contrary to Article 1(2) of the Directive on the obligations which the EPC imposes on the Member States.

62. However, the applicant in no way indicates in what respect the slightly different wording used by the Directive on that point, inspired by the wording of Article 27(3) of the TRIPS Agreement, requires Member States to breach their obligations under the EPC in order to comply with their obligations under the Directive. In the absence of specific examples to the contrary, it seems reasonable to suppose that a breach of ordre public and morality as regards a specific invention could be equally well established by reference to its publication, exploitation or commercial exploitation.

63. Fourthly and finally, the applicant and, to a greater extent, the Norwegian Government intervening in its support submit that the very purpose of the Directive, which is to make biotechnological inventions patentable in all the Member States, runs counter to the principle of equitable sharing of the benefits arising out of the utilisation of genetic resources, which is one of the objectives of the CBD.

64. However, the risks described by the applicant and that intervener are expressed in hypothetical terms and are not derived directly from the provisions of the Directive but, at the very most, from the use which might be made of them.

65. It cannot be assumed, in the absence of evidence, which is lacking in this case, that the mere protection of biotechnological inventions by patent would result, as is argued, in depriving developing countries of the ability to monitor their biological resources and to make use of their traditional knowledge, any more than it would result in promoting single-crop farming or in discouraging national and international efforts to preserve biodiversity.

66. Moreover, while Article 1 of the CBD states that its objective is the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, it specifies that this must be done taking into account all rights over those resources and technologies. There is no provision of the CBD which requires that the conditions for the grant of a patent for biotechnological inventions should include the consideration of the interests of the country from which the genetic resource originates or the existence of measures for transferring technology.

67. Finally, as regards the possibility that the Directive might represent an obstacle in the context of the international cooperation necessary to achieve the objectives of the CBD, it should be borne in mind that, under Article 1(2) of the Directive, the Member States are required to apply it in accordance with the obligations they have undertaken as regards inter alia biological diversity.

68. It follows from the foregoing that the fourth plea must be rejected.

The fifth plea

69. The applicant submits that the patentability of isolated parts of the human body provided for by Article 5(2) of the Directive reduces living human matter to a means to an end, undermining human dignity.

Moreover, the absence of a provision requiring verification of the consent of the donor or recipient of products obtained by biotechnological means undermines the right to self-determination.

70. 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.

71. As regards respect for human dignity, this is guaranteed in principle by Article 5(1) of the Directive which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention.

72. Nor are the elements of the human body 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.

73. Thus, as is stated in the 20th and 21st recitals of the preamble to the Directive, 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.

74. 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.

75. 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.

76. Additional security is offered by Article 6 of the Directive, which cites as contrary to ordre public and morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. The 38th recital of the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offend against human dignity are also excluded from patentability.

77. It is clear from those provisions that, as regards living matter of human origin, the Directive 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.

78. The second part of the plea concerns the right to human integrity, in so far as it encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient.

79. Reliance on this fundamental right is, however, clearly 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.

80. The grant of a patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products, as the 14th recital of the preamble to the Directive points out. The purpose of the Directive is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent.

81. The fifth plea must, therefore, be rejected.

The sixth plea

82. Finally, the applicant argues that the Directive is vitiated by breach of procedural rules in that it gives no indication that the Commission's proposal was adopted by a college of members on the basis of a text available in all the official languages.

83. The Council takes the view that this plea is inadmissible in so far as the applicant does not make clear whether it relates to the original proposal or the amended proposal of the Commission and furnishes no evidence in support of its plea.

84. However, since the Directive states, in the preamble, that it concerns the Commission proposal, referring in a footnote to the editions of the Official Journal of the European Communities of 8 October 1996 and 11 October 1997, the plea must be taken to concern both the proposal for a directive 96/C 296/03 submitted by the Commission on 25 January 1996 (OJ 1996 C 296, p. 4), and the amended proposal for a directive 97/C 311/05 submitted by the Commission on 29 August 1997 (OJ 1997 C 311, p. 12). The plea is also sufficiently clear for the Court to be able to understand its scope.

85. After the Commission had provided, in its statement in intervention, information to establish that the principle of collegiality and the rules regarding languages applicable to its deliberations had been respected, the applicant explained that its plea did not allege breach of the principle of collegiality as such but the lack of any apparent proof, in the wording of the Directive, that the principle was respected.

86. In that regard, 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.

87. 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. It has not been established, or even alleged, that the Parliament or the Council had valid reasons for believing that the Commission's examination of its proposal did not follow the proper procedures in this case.

88. The sixth plea, and the application in its entirety, must, therefore, be rejected.

Costs

89. Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Parliament and the Council have applied for an order that the Kingdom of the Netherlands bear the costs and it has been unsuccessful, it must be ordered to pay the costs.

90. Pursuant to the first and second subparagraphs of Article 69(4) of those rules, the Italian Republic, the Kingdom of Norway and the Commission, which have intervened in the proceedings, are to bear their own costs.

On those grounds,

THE COURT

hereby:

1. Dismisses the application;

2. Orders the Kingdom of the Netherlands to bear the costs;

3. Orders the Italian Republic, the Kingdom of Norway and the Commission of the European Communities each to bear their own costs.

Rodríguez Iglesias
Jann
Macken
Colneric
von Bahr
Gulmann
Edward
La Pergola
Puissochet
Sevón
Wathelet
Skouris
Cunha Rodrigues

Delivered in open court in Luxembourg on 9 October 2001.

Registrar
R. Grass

President
G.C. Rodríguez Iglesias

(1) Language of the case: Dutch.