# OPINION OF ADVOCATE GENERAL JACOBS
## delivered on 14 June 2001 [1]

Table of contents


The Directive ..... I-7085

The action for annulment ..... I-7087

The context of the Directive — patent law ..... I-7089

The context of the Directive — biotechnology ..... I-7092

The arguments as to legal basis ..... I-7095

The relevant recitals and provisions of the Directive ..... I-7095

The arguments that obstacles to trade have not been shown ..... I-7098

The argument that Community harmonisation is inappropriate and ineffective ..... I-7100

The argument that Articles 130 and 130f, together with Article 235, were the correct legal basis ..... I-7102

The argument that the Directive infringes Article 100a(3) ..... I-7104

The argument that the Directive creates a new intellectual property right ..... I-7105

The argument as to subsidiarity ..... I-7108

The argument as to legal certainty ..... I-7109

The arguments as to Article 6 ..... I-7111

The relevant recitals and provisions of the Directive ..... I-7111

Are ordre public and morality sufficiently clear concepts? ..... I-7112

What is the meaning and purpose of the proviso in Article 6(1)? ..... I-7116

Does ordre public encompass prejudice to the environment? ..... I-7117

What is the status of recital 38? ..... I-7118

The argument as to plant and animal varieties ..... I-7119

The relevant recitals and provisions of the Directive ..... I-7119


1 — Original language: English.

The argument as to Articles 8 and 9 ..... I-7121
The argument that 'animal varieties' is not defined ..... I-7123
The arguments as to recitals 31 and 32 and Article 4(1)(a) and 4(2) ..... I-7124
The argument as to the infringement of international obligations ..... I-7126
Infringement of the TRIPs Agreement ..... I-7128
Incompatibility with the Agreement on Technical Barriers to Trade ..... I-7129
Incompatibility with the European Patent Convention ..... I-7131
Incompatibility with the Convention on Biological Diversity ..... I-7132
The argument as to fundamental rights ..... I-7137
Does Article 5(2) infringe fundamental rights? ..... I-7140
Does the failure to provide for consent infringe fundamental rights? ..... I-7142
The argument that the correct procedure was not followed ..... I-7145
Conclusion ..... I-7147

1. In this case the Netherlands has brought an action under Article 173 of the EC Treaty (now, after amendment, Article 230 EC) seeking annulment of Directive 98/44/EC on the legal protection of biotechnological inventions. [2]

## The Directive

2. Chapter I (Articles 1 to 7) of the Directive is entitled 'Patentability'.

3. The Directive requires Member States to protect biotechnological inventions under national patent law. [3] Although there is no definition of 'biotechnological inventions', it is clear that the concept essentially comprises inventions concerning 'a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used' [4] or inventions concerning 'a microbiological or other technical process or a product obtained by means of such a process'. [5] 'Microbiological process' is defined as 'any process involving or performed upon or resulting in microbiologi-

2 — Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, OJ 1998 L 213, p. 13.

3 — Article 1(1).
4 — Article 3(1).
5 — Article 4(3).

cal material'.[6] 'Biological material' is defined as 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'.[7] Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature;[8] similarly an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[9]

4. The Directive provides that the following may not be patented: (i) plant and animal varieties;[10] (ii) essentially biological processes for the production of plants or animals;[11] (iii) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;[12] and (iv) inventions the commercial exploitation of which would be contrary to *ordre public* or morality.[13] Examples of the latter are (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; and (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes.[14]

5. Chapter II of the Directive (Articles 8 to 11) concerns the scope of protection conferred by a patent. Chapter III (Article 12) concerns compulsory cross-licensing.[15] Chapter IV (Articles 13 and 14) concerns the deposit and re-deposit of and access to a biological material. Chapter V (Articles 15 to 18) contains final provisions. The provisions of these chapters are referred to below as appropriate.

6. The Directive has a relatively long history, although the version finally adopted went through the legislative process with impressive speed.

7. In 1988 the Commission presented its first proposal for a Council Directive on the legal protection of biotechnological inventions.[16] The proposed Directive started from the premiss that a 'subject matter of an invention shall not be considered unpatentable for the reason only that it is

6 — Article 2(1)(b).
7 — Article 2(1)(a).
8 — Article 3(2).
9 — Article 5(2).
10 — Article 4(1)(a).
11 — Article 4(1)(b).
12 — Article 5(1).
13 — Article 6(1).
14 — Article 6(2).
15 — See note 139.
16 — COM(88) 496 of 17 October 1988; OJ 1989 C 10, p. 3.

composed of living matter'. [17] That proposal ultimately foundered, principally because of the Parliament's resistance to an instrument which articulated no fundamental ethical principles governing the grant of patents in the context of animate matter.

8. In 1996 the Commission presented a fresh proposal. [18] After substantial amendments proposed by the Parliament, it was adopted on 6 July 1998. The Netherlands voted against the Directive; Italy and Belgium abstained. The Directive required implementation by 30 July 2000. [19]

9. There are 56 recitals in the preamble to the Directive as adopted, [20] in contrast to a mere 18 articles, not all substantive. Many of the recitals are clearly designed to counter objections raised by the Parliament, both to the 1996 proposal and to the 1988 proposal. Not all the recitals are reflected in the articles of the Directive. The recitals and the substantive provisions of the Directive are considered further below in the context of the various heads of the Netherlands' claims.

17 — Article 2.

18 — Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, COM(95) 661 of 13 December 1995; OJ 1996 C 296, p. 4.

19 — Article 15(1).

20 — Some of the more relevant recitals are set out in paragraphs 42, 91, 113, 149, 167 and 186 below.

## The action for annulment

10. The Netherlands has challenged the validity of the Directive. It is clear from its application that its objection is in essence to the notion that plants, animals and parts of the human body may be patentable. The Netherlands considers that the right to a patent in the field of biotechnology should be limited to the biotechnological process and not extended to the products deriving therefrom: in other words, neither plants and animals as such, including genetically modified plants and animals, nor human biological material should be patentable.

11. The grounds invoked for the annulment of the Directive are that it (i) is incorrectly based on Article 100a of the Treaty; (ii) is contrary to the principle of subsidiarity; (iii) infringes the principle of legal certainty; (iv) is incompatible with international obligations; (v) breaches fundamental rights; and (vi) was not properly adopted since the definitive version of the proposal submitted to the Parliament and the Council was not decided on by the college of Commissioners.

12. As will be seen, some of the above grounds concern the interpretation and effect of the Directive in technical areas: thus for example the second head of the third ground questions the scope of the exclusion from patentability of plant and animal varieties. Other grounds raise sub-

stantive issues of broader import, such as the compatibility of the Directive with fundamental rights and with other international obligations. Finally, the first, second and sixth grounds concern more formal issues relating to the adoption of the Directive. Even those grounds, however, involve important issues of principle: one of the arguments in the context of the correct legal basis, for example, raises the question whether the Directive, by providing for a 'patent on life', creates a new intellectual property right. I propose to deal with the grounds for annulment in the order in which the Netherlands has presented them in its application, although other approaches can equally be envisaged.

13. The Netherlands is supported by Italy (whose written observations in intervention focus on the first and third grounds for annulment) and Norway (whose observations focus on the first, third and fourth grounds). The Parliament and Council are supported by the Commission (whose observations are limited to the sixth ground).

14. Two procedural matters should be mentioned at this point.

15. First, on 6 July 2000 the Netherlands lodged an application for interim measures, principally seeking suspension of operation of the Directive until the Court had ruled on the application for annulment. The European Parliament and the Council submitted written observations on the application for interim measures. A hearing was held on 18 July 2000 at which the Netherlands, the Parliament and the Council together with Italy and the Commission, which had both been granted leave to intervene, were present. The application for interim measures was dismissed by order of the President of the Court of 25 July 2000.

16. Second, the Council and the Parliament submit as a preliminary point that Norway's statement in intervention is inadmissible. Article 37 of the Statute of the Court of Justice requires an application to intervene by a State which is party to the Agreement on the European Economic Area to be limited to supporting the form of order sought by one of the parties. Article 93(5)(a) of the Rules of Procedure of the Court similarly requires that the statement in intervention contain a statement of the form of order sought by the intervener in support of or opposing, in whole or in part, the form of order sought by one of the parties. In the present case, the Netherlands seeks the annulment of the Directive. In the introduction to its statement in intervention, Norway states that the Netherlands 'raises several questions which may have a bearing on whether or not the Directive falls within the area covered by the EEA Agreement, and on the implementation of the Directive into the EEA Agreement'. It is nowhere stated that Norway is intervening in support of the form of order sought by the Nether-

lands. The conclusion of the statement in intervention is as follows:

'Several of the questions presented by the Government of the Netherlands in its action for annulment of Directive 98/44/EC 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. Norway, therefore, respectfully requests that the Court take due account of the arguments set forth herein.'

17. The Council adds that in any event Norway's observations in intervention have been largely overtaken by events, since Article 3(4) of Protocol 28 to the EEA Agreement requires the EFTA States to comply in their law with the substantive provisions of the European Patent Convention and since those provisions now include the provisions of the Directive (see further below).

18. I do not agree with the Council and the Parliament that Norway's statement in intervention is inadmissible. Norway explicitly stated in its application to intervene that it wished to intervene in support of the Netherlands. It is apparent from its statement in intervention, even if it is not explicitly stated, that Norway supports the Netherlands' arguments that Article 100a was the incorrect legal basis for the Directive, that the Directive infringes the principle of legal certainty and that it is incompatible with the Convention on Biological Diversity. It is also stated that the effect of such incompatibility is in the view of Norway that the Directive would have to be 'repealed', which may be taken to mean 'annulled', and that the consequence of the infringement of the principle of legal certainty is that the Directive should be annulled. I accordingly consider that Norway's statement in intervention is admissible.

## The context of the Directive — patent law

19. A patent is a legal right conferred on an inventor in respect of a specific invention and entitling him to prevent others from making, using or selling the invention for the duration of the patent. Most developed legal systems have had a system of patent law for some time. The earliest known English patent, for example, was granted by Henry VI to Flemish-born John of Utynam in 1449. The patent conferred a 20-year monopoly for a method of making stained glass, required for the windows of Eton college, that had not been previously known in England.

20. Modern patent systems tend to impose more or less uniform requirements for the grant of a patent. Those requirements may be illustrated by the European Patent Convention, which came into force in 1978. Although not a Community instrument,[21] since all Member States of the Union are parties to the Convention it in effect unifies the conditions for the grant of a patent throughout the Union.

21. The Convention establishes a 'system of law, common to the Contracting States, for the grant of patents for invention'.[22] A patent granted by virtue of the Convention is called a European patent and in each Contracting State for which it is granted[23] has the effect of and is subject to the same conditions as a national patent granted by that State.[24] Enforcement of a patent granted by virtue of the Convention is thus regulated not by the Convention but by national law and procedure.

22. A European patent is to be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.[25] A European patent is not however to be granted in respect of:

'(a) inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.'[26]

23. The same criteria are used to define patentable subject-matter in the TRIPs

21 — The Contracting States are currently the 15 EU Member States plus Switzerland, Liechtenstein, Monaco, Cyprus and Turkey.

22 — Article 1.

23 — The applicant must specify at least one Contracting State.

24 — Article 2.

25 — Article 52(1), reproducing verbatim the first sentence of Article 1 of the 1963 Strasbourg Convention on the unification of certain points of substantive law on patents for invention. That Convention drew extensively upon the preparatory work (dating back to 1950) undertaken by the Scandinavian countries on a Nordic patent law (subsequently superseded by the European Patent Convention) and on the work of the six original EEC Member States on a common European patent law.

26 — Article 53, reproducing verbatim Article 2 of the Strasbourg Convention.

Agreement, [27] although the exclusions from patentability are there set out as options.

24. A further feature common to modern patent systems is a requirement that the patent application disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. [28] The description must include a detailed account of at least one way of carrying out the invention claimed and a statement of how the invention is capable of industrial application. [29] Since patent applications are normally published, [30] the sum of knowledge in the public domain is increased with each patent. Although that knowledge cannot of course be used by a third party for the duration of the patent to reproduce the invention, since that will normally constitute infringement, it can be built on and lead to further inventions.

25. Once conferred, a patent merely entitles the holder to prevent others from making, using or selling the patented invention in the territory in which the patent has effect. It confers no right of ownership as such, nor any absolute right to manufacture or otherwise exploit the invention. Thus the holder of a patent will still need to comply with national law when he makes, uses or sells his invention. [31] He may for example need to obtain a licence or authorisation; he may even patent an invention (a type of weapon for example) the making, use or sale of which is prohibited by national law.

26. An example illustrates this point. Suppose that a superior type of copying machine were patented and that its enhanced performance meant that it could produce high quality counterfeit bank notes. The existence of a patent (which would be granted under most patent systems, including the European Patent Convention, on the basis that not all uses of the invention were contrary to *ordre public* or morality [32]) would not of course legalise such use.

27. Normally, only exploitation for industrial and commercial purposes constitutes infringement of a patent, and patent laws specify that certain acts do not constitute infringement. Experimental use is one such exception: experiments aimed at perfecting, improving or further developing protected inventions do not infringe the patent.

27 — Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement), OJ 1994 L 336, p. 213.

28 — European Patent Convention, Article 83; TRIPs Agreement, Article 29(1).

29 — Rule 27(1)(c) and (f) of the Implementing Regulations to the Convention on the grant of European patents.

30 — See for example Article 93 of the European Patent Convention.

31 — See generally recital 14 in the preamble to the Directive, set out in paragraph 42 below.

32 — See Guidelines for examination in the European Patent Office, as last amended in February 2001, Part C, Chapter IV, paragraph 3.3.

## The context of the Directive — biotechnology

28. 'Biotechnology' is defined in the 1993 edition of the *Shorter Oxford English Dictionary* [33] as 'the industrial application of biological processes'. The *Encyclopaedia Britannica* defines it as 'the application to industry of advances made in the techniques and instruments of research in the biological sciences'. For the purposes of the Convention on Biological Diversity [34] it is defined as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. [35]

29. Biotechnology in that broad sense is as old as bread, wine, beer and cheese. Historically, biotechnological inventions such as processes using yeasts and fermentation [36] were typically regarded as patentable: [37] there was thus no general prohibition on patents involving such basic types of living matter although more sophisticated living matter was normally excluded from patentability by express provision or case-law.

30. Biotechnology in the modern sense of genetic manipulation was made possible by the remarkable advances in biochemistry, molecular biology and genetics in the latter half of the 20th century. The discovery in 1953 by Francis Crick and James Watson of the structure of DNA [38] paved the way for further discoveries. Each DNA molecule is constructed as a double helix, or paired spirals, linked by bases of which there are four kinds. The nucleus of a cell

33 — It had no entry in the previous edition.

34 — Signed by the Community and all the Member States at the United Nations Conference on Environment and Development in Rio de Janeiro on 5 June 1992; Annex A to Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity, OJ 1993 L 309, p. 1.

35 — Article 2.

36 — The discovery that yeasts were living cells was first made by a French and a German scientist (independently) in 1836 and 1837; it was initially ridiculed but subsequently accepted when described in 1858 by Pasteur. In 1871 two applications for patents were made to the UK Patent Office for a formula for self-raising flour comprising flour and dried yeast. In 1873 the US Patent Office granted Pasteur a patent on 'yeast, free from organic germs of disease, as an article of manufacture'. In 1883 Hansen, then director of the Carlsberg brewery in Copenhagen, who had succeeded in growing pure cultures of yeast from single cells, used one of his cultures to ferment a batch of beer after the original yeast used had spoiled. The owner of the brewery refused to patent the culture process; it was accordingly published and used by most breweries in Europe and America.

37 — Although Australia granted its first patent for a living organism, a yeast strain having improved properties for bread making, only in 1976.

38 — Deoxyribonucleic acid.

contains several threads of DNA, called chromosomes. A gene is a segment of a chromosome, and hence a length of DNA, which contains the instructions to make a part of a protein. The sequence of the bases of the DNA contained in a cell makes up the genetic code of that cell. Cells need numerous different proteins in order to develop and function. Genes are responsible for particular proteins with their own function in living cells. When instructing a cell how to make a particular protein, part of the DNA helix is temporarily 'unzipped' (the two strands separate) so that an imprint of its code may be copied into an RNA molecule (ribonucleic acid). That copy moves out of the nucleus and instructs the cell to assemble a protein or part of a protein.

31. DNA is present in all organisms (except for some viruses); it is accordingly possible to transfer a gene between unrelated species and even across genera and orders, for example between plants, bacteria, humans and other animals. Thus in principle any genetic characteristic of one organism can be transferred to another organism.

32. In the 1970s a method was discovered of extracting specific genes and parts of genes from chromosomes by restriction [39] enzymes, which like biological scissors excise a fragment of DNA from a cell. The DNA can then be inserted into bacterial, viral or yeast cells by a laboratory procedure. A single gene (or several genes) can accordingly be transferred between organisms. The cells incorporating the foreign DNA can be grown in enormous numbers, cloning the imported fragment of DNA.

33. This type of recombinant DNA genetic engineering has made possible a number of processes of unquestionable benefit to mankind, [40] such as the large-scale production of insulin for treating diabetes, [41] interferon and other drugs for treating certain cancers, vaccines against diseases such as hepatitis B, the human growth hormone for the treatment of certain forms of dwarfism and the clotting factor missing in haemophilia.

34. Gene transfer is a different method of gene technology. Segments of DNA containing a specific gene or genes are first isolated as above and then incorporated into the DNA of a fertilised egg or, later,

39 — So called because they target a restricted segment of DNA.

40 — And indeed to animals, since several vaccines have been engineered, for example against foot and mouth disease and cattle ticks. Creations of broader environmental benefit include bacteria used to biodegrade oil spills and toxic waste.

41 — Developed in 1982.

into embryonic cells. The new gene will be present in the adult organism and will be inherited by some descendants of that organism.

35. Cloning is a process whereby the nucleus of an unfertilised egg is removed and replaced with the nucleus of a somatic cell (namely a cell from an animal or plant other than the reproductive cells), which contains all the genetic material. If the treated egg survives and develops, the resulting animal will be a genetic clone of the animal which was the source of the somatic cell.

36. The biotechnological industry began to develop seriously after a decision by the US Supreme Court in 1980 that 'a live, human-made micro-organism is patentable subject matter'. [42] That case concerned an invention of a human-made, genetically engineered bacterium capable of breaking down crude oil. The Supreme Court held (by a 5:4 majority) that the micro-organism constituted a 'manufacture' or 'composition of matter' within the meaning of the Patent Act 1952. [43] The Court noted that the Committee Reports accompanying the 1952 Act indicated that Congress intended statutory subject matter to 'include anything under the sun that is made by man'. [44]

37. That ruling prompted the establishment of a number of commercial firms that manufacture quantities of gene-engineered substances for a variety of mostly medical and ecological uses.

38. In the 1980s Harvard University applied under the European Patent Convention for a patent for a mouse genetically engineered to contain a gene sequence making it more susceptible to cancer. In 1990 the Technical Board of Appeal of the European Patent Office ruled that the exception to patentability under Article 53(b) of the European Patent Convention [45] applied to certain categories of animals but not to animals as such: it noted that Article 53(b), as an exception, must be narrowly construed. The patent was accordingly granted. [46]

39. Developments in genetic engineering have caused concern in many quarters.

42 — *Diamond* v. *Chakrabarty*, 447 US 303 (1980).

43 — The wording derived unchanged from the first Patent Act of 1793, authored by Thomas Jefferson.

44 — The first patent for a micro-organism in Japan was granted the following year. It may be significant that apparently there is no overriding ground of exclusion from patentability on ethical or moral grounds in either the US or Japan (although in the US at least ethical considerations may be relevant to determining whether the utility criteria is satisfied).

45 — Set out in paragraph 22 above.

46 — A patent was also granted in the US in 1988.

Clearly technology which enables the genetic make-up of animals and humans to be modified and which has the potential to create human clones calls for careful regulation. Much of the understandable anxiety about the consequences of insufficiently regulated research in the field has been directed against legislation — such as the Directive — which governs the patentability of such inventions. Many commentators start from the assumption that such legislation means that any gene or gene sequence, or even the entire human genome, can now automatically be patented. That assumption is incorrect. The Directive leaves untouched the classic requirements for a patent of novelty, inventive step and industrial application.[47] The mere discovery of a gene or gene sequence is no more patentable under the Directive than it was before.

The arguments as to legal basis

40. The Directive is based on Article 100a of the Treaty (now, after amendment, Article 95 EC), paragraph 1 of which requires the Council to adopt, by qualified majority and in accordance with the codecision procedure laid down in Article 189b (now Article 251 EC), measures for the 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.

41. The Netherlands, supported by Italy, submits that Article 100a is not the correct legal basis for the Directive on several grounds and that, if it was considered necessary to regulate biotechnological inventions, Article 235 of the EC Treaty (now Article 308 EC), which requires unanimity, should have been used.

*The relevant recitals and provisions of the Directive*

42. The preamble to the Directive includes the following recitals:

'(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;

47 — See Article 3(1), set out in paragraph 187 below. Article 5(3) further provides that the 'industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application'.

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

...

(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or [as] national case-law interpreting such legislation develops differently;

(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

(8) Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;

(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts in national laws based upon international patent and plant variety conven-

tions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

...

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards'.

43. Article 1 of the Directive provides:

'1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of the Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.'

44. Article 11 of the Directive provides:

'1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of

pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.'

*The arguments that obstacles to trade have not been shown*

45. First, the Netherlands submits that, even if it is assumed that, as stated in recitals five and six in the preamble, there are actual or potential differences in national laws on the patenting of biotechnological inventions, it has not been proved that such differences in fact hinder or can hinder trade. Even if they did, the obstacles would be to trade with the United States and Japan, where the manufacture and patenting of biotechnological inventions is more advanced, and not within the internal market. In the absence of any evidence of differences in national laws or of effect on trade, harmonisation by way of a directive cannot be justified.

46. The Council and the Parliament refer to the Court's ruling in *Spain* v *Council* [48] that recourse to Article 100a is justified where 'harmonising measures are necessary to deal with disparities between the laws of the Member States in areas where such disparities are liable to create or maintain distorted conditions of competition [or] in so far as such disparities are liable to hinder the free movement of goods within the Community'. In that case, the Court confirmed the validity of a regulation concerning the creation of a supplementary protection certificate for medicinal products [49] adopted on the basis of Article 100a. The Court noted that, according to the Council, at the time the contested regulation was adopted provisions concerning the creation of a supplementary protection certificate for medicinal products existed in two Member States and were at the draft stage in another State. The regulation was intended to establish a uniform Community approach. [50] It thus aimed 'to prevent the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and functioning of the internal market'. [51]

47. I would note that the above principles laid down in *Spain* v *Council* have more recently been refined by the Court in

48 — Case C-350/92 [1995] ECR I-1985, paragraphs 32 and 33 of the judgment.

49 — Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ 1992 L 182, p. 1.

50 — Paragraph 34 of the judgment.

51 — Paragraph 35 of the judgment.

*Germany* v *Parliament and Council*.[52] In that case the Court stated that, while recourse to Article 100a as a legal basis was possible if the aim was to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them.[53] With regard to the measure's effect on competition, the Court stated that it was required to verify whether the distortion of competition which the measure purported to eliminate was 'appreciable'[54] and thus whether the measure actually contributed to eliminating appreciable distortions of competition.[55] With regard to the measure's effect on the free movement of goods, the Court appears to have been less exacting: it is sufficient that obstacles to free movement 'may well arise'.[56] Although it had been demonstrated that no obstacle existed at the material time, the Court accepted that 'in view of the trend in national legislation... it is probable that obstacles to the free movement of... products will arise in the future'[57] and that in principle a harmonising measure could be adopted on the basis of Article 100a.[58]

48. The Court has made it clear since an early stage that, in the absence of harmonisation, the national character of the protection of industrial property and the variations between the different legislative systems are capable of creating obstacles both to the free movement of patented products and to competition within the common market.[59] It has moreover consistently recognised that the specific subject matter of a patent is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, as well as the right to oppose infringements.[60] Patents thus promote competition through innovation. Indeed the Netherlands implicitly recognises this, noting that the manufacture of biotechnological inventions is more advanced in the United States and Japan where, as mentioned above, biotechnological inventions have been readily patentable since 1980 and 1981 respectively.[61] Heterogeneous and potentially or actually divergent national laws on legal protection, patentability, the extent of protection, derogations and limitations are clearly liable to distort competition within the Community and moreover to hinder the free movement of goods. Different levels of protection for an identical product would lead to fragmentation of the market into national markets where the product would be protected and others where it would not; the common market would not be a single environment for the economic activities of undertakings. The Court has explicitly recognised this in the context of intellectual property rights.[62]

52 — Case C-376/98 [2000] ECR I-8419 (tobacco advertising).
53 — Paragraph 86 of the judgment.
54 — Paragraph 106 of the judgment.
55 — Paragraph 108 of the judgment.
56 — Paragraph 96 of the judgment.
57 — Paragraph 97 of the judgment.
58 — Paragraph 98 of the judgment.
59 — See for example Case 24/67 *Parke, Davis* [1968] ECR 55, p. 71.
60 — See for example Case 15/74 *Centrafarm and De Peijper* [1974] ECR 1147, paragraph 9 of the judgment.
61 — See note 44.
62 — *Spain* v *Council*, cited in note 48, paragraph 36 of the judgment.

49. I accordingly conclude that the Council and Parliament were entitled to take the view that a harmonising measure was necessary to deal with disparities between the laws of the Member States concerning the patent protection of biotechnological inventions.

*The argument that Community harmonisation is inappropriate and ineffective*

50. With regard to the Netherlands' argument that the Directive seeks in particular to make European industry more competitive vis-à-vis the United States and Japan, I agree with the Parliament that it is consistent with Article 100a that the harmonisation sought should improve the competitive position of European undertakings on the world market. Although that objective could be seen as an industrial policy objective, I have no doubt that it can lawfully guide the Community's action. Some would argue that similar considerations underlie the entire internal market programme, as it was conceived in 1985, and competition in world markets has often been said to motivate that programme. I would also point out that the EC Treaty now [63] contains a title on industry, according to which the action of the Community and of the Member States shall also be aimed at 'fostering better exploitation of the industrial potential of policies of innovation, research and technological development' (Article 130(1), now Article 157(1) EC). In Article 130(3) of the EC Treaty (now Article 157(3) EC) it is further stated that the Community 'shall contribute to the achievement of the objectives set out in paragraph 1 through the policies and activities it pursues under other provisions of this Treaty'.

51. The Netherlands' second argument is based on the fact that recital 9 in the preamble refers to uncertainty deriving from international patent and plant variety conventions as a justification for harmonisation. The Netherlands submits that it is not for the European Union to undertake such harmonisation. It would have been preferable on several grounds to harmonise by amending the European Patent Convention, which would have effected more extensive harmonisation since States other than the Member States of the European Union are Contracting Parties. [64] As it is, that convention now incorporates the Directive (by way of implementing regulations made by the Administrative Council of the European Patent Office [65]), which is thus imposed on those Contracting Parties who are not Member States. Such a proce-

63 — Since the entry into force of the Treaty on European Union.

64 — See note 21.

65 — The decision of the Administrative Council of 16 June 1999 amended the Implementing Regulations to the European Patent Convention by inserting a new Chapter VI entitled 'Biotechnological inventions' containing provisions essentially identical to Articles 2, 3, 4(2) and (3), 5 and 6(2) of the Directive and providing that the Directive shall be used as a supplementary means of interpretation.

dure has no place in the external relations of the Union with other European States.

52. That argument is to my mind misconceived, although as the Council suggests it appears implicitly to recognise that harmonisation in the area is necessary. In the context of the internal market, however, it is evident that Community legislation alone can guarantee harmonisation and uniform interpretation. Harmonisation at Community level not infrequently takes place against a background of international conventions the parties to which include both the Member States of the Union and third countries: in the area of intellectual property, for example, the Trade Marks Directive [66] has some overlap with earlier agreements such as the Paris Convention for the protection of industrial property [67] and the Madrid Agreement concerning the international registration of marks. [68] The existence of that context does not however deprive the Community institutions of the competence in the area conferred upon them by the Treaty.

53. Moreover I agree with the Parliament that in any event amendment of the Convention, even if feasible given the cumbersome procedure [69] and the involvement of third countries, would not guarantee harmonisation for two reasons in particular. First, in proceedings at national level to annul a European patent divergences of interpretation would develop, in contrast to the position under the Directive where national courts can refer questions of interpretation to the Court of Justice. Second, the Convention does not concern the extent of protection conferred by a patent, which is essential with regard to biotechnology and which is governed by national law. Furthermore those points themselves provide further support for the view that the Convention not merely 'would not guarantee harmonisation' but is simply irrelevant for this aspect of the Directive, since important areas of patent law governed by the Directive are outside its scope.

54. As for the fact — criticised by the Netherlands — that the European Patent Convention now incorporates certain provisions of the Directive by means of a decision of the Administrative Council amending the Implementing Regulations, [70] which are thus imposed on those contracting parties who are not Member States, it is not for the Court to rule on the manner in which the European Patent Office has chosen to reflect the Directive in its law

66 — First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, OJ 1989 L 40, p. 1.

67 — Of 20 March 1883, as revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967.

68 — Of 14 April 1891, as revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, at London on 2 June 1934, at Nice on 15 June 1957, and at Stockholm on 14 July 1967, and as amended on 28 September 1979.

69 — Article 172 of the Convention.

70 — See note 65.

and practice. It may however be thought that that choice suggests that the Patent Office, which has considerable experience in handling applications for patents for biotechnological inventions, does not anticipate major problems in the interpretation or application of the provisions of the Directive concerning the grant of such patents.

55. Italy adds that the fact that the Directive leaves scope for non-harmonised national rules regulating in particular public health, safety and environmental protection [71] militates against the Directive's contributing to the free movement of the products concerned. That argument is in my view similarly based on a misconception of the function of patent law. As has been discussed above, [72] a patent is a right merely to prevent others from infringing the patent and does not confer any absolute entitlement on the proprietor to exploit the patent: exploitation is always subject to national regulation. Many of the Court's rulings to the effect that an exercise of national patent rights which restricts the free movement of goods is contrary to Article 28 EC and hence unlawful concern patented pharmaceutical products: the fact that the marketing and use of such products is rigorously regulated in all Member States at the national level does not diminish the importance of the principle of the free movement of goods in limiting the exercise of national patent rights. Nor indeed does it mean that Community legislation for the harmonisation of national laws relating to supplementary protection certificates, which confer protection akin to patent protection, is misconceived, ineffective or unlawful. [73]

56. I accordingly do not accept the argument that Community harmonisation is inappropriate and ineffective.

*The argument that Articles 130 and 130f, together with Article 235, were the correct legal basis*

57. Italy submits first that the aims of the Directive go beyond harmonisation, including objectives linked to support for industrial development in the Community and for scientific research in the genetic engineering sector. In support of that argument it refers to recitals one to three in the preamble to the Directive. Other provisions of the Treaty (Articles 130 and 130f (now Articles 157 and 163 EC)) are appropriate

71 — See recital 14, set out in paragraph 42 above.

72 — See paragraph 25 above.

73 — *Spain* v *Council*, cited in note 48.

for legislation in the sectors of industry and research respectively, in conjunction with Article 235. The functioning of the internal market is a secondary objective of the Directive, which should therefore not have been based on Article 100a. [74]

58. The Court has made it clear that the choice of the legal basis for a measure must be based on objective factors which are amenable to judicial review, including in particular the aim and content of the measure as they appear from its actual wording. [75] Where moreover a measure pursues more than one objective, its principal objective is decisive for determining the correct legal basis. [76]

59. The first three recitals in the preamble to the Directive do indeed refer to the importance of the protection of biotechnological inventions for the Community's industrial development, research and development in the field of genetic engineering and investment in the field of biotechnology. Recitals 5 to 7 however stress the need for the elimination of differences in national law on the protection of biotechnological inventions which could create barriers to trade and hence impede the proper functioning of the internal market. Recital 7 in particular states that disincentives to trade flowing from the uncoordinated development of national law would be 'to the detriment of the industrial development of such inventions and of the smooth operation of the internal market', thus linking the two aims. Recitals 8 and 9 make further reference to the harmonising aim of the Directive.

60. More fundamentally, it appears that, although the laws of all Member States concerning the conditions for the grant of a patent and the exceptions to patentability broadly reflect the European Patent Convention and are thus to some extent already aligned, there are none the less significant differences in some areas of national law and practice. It appears for example that some Member States already grant patents for biotechnological inventions involving animals: in France, for example, a patent was granted in 1991 for a process for producing a transgenic [77] mouse [78] and in Italy the first patent concerning a transgenic mammal was granted in 1996. [79] The

74 — Case C-155/91 *Commission* v *Council* [1993] ECR I-939 (waste disposal), paragraph 19 of the judgment.

75 — See e.g. Case C-300/89 *Commission* v *Council* [1991] ECR I-2867 (titanium dioxide), paragraphs 10 and 13 of the judgment.

76 — See for example *Commission* v *Council*, cited in note 74.

77 — Genetically modified to include a gene from another species.

78 — Mentioned in F. Pollaud-Dulian, *La brevetabilité des inventions* (1997), paragraph 244.

79 — Mentioned by G.M. Gradi in 'Patenting biotechnologies: the European Union Directive 98/44/EC of the European Parliament and of the Council of 6th July 1998 on the legal protection of biotechnological inventions' (retrieved from internet).

Parliament gives other examples of divergences in national law and practice the existence of which is not disputed by the Netherlands.

61. That harmonisation is the principal aim of the Directive is moreover borne out by its content: indeed Article 1(1) unequivocally requires Member States to adjust their national patent law to take account of its provisions. The extent to which the provisions of the Directive will affect industrial development in the Community and scientific research in the genetic engineering sector is more difficult to assess. What seems clear however is that the impact of the Directive on those areas is indissociably linked with its harmonising effect.

62. Although Articles 130 and 130f confer powers on the Community to undertake specific action in the fields they cover, they do not confer any legislative power and they leave intact the powers held by the Community under other provisions of the Treaty, even if the measures to be taken under the latter provisions pursue at the same time any of the objectives falling within Articles 130 and 130f. [80]

80 — See by analogy Case C-62/88 *Greece* v *Council* [1990] ECR I-1527, in particular paragraph 19 of the judgment.

63. In the present case, I consider that harmonisation is not an incidental or ancillary aim or effect of the Directive but is its essence and that Article 100a was accordingly the correct legal basis. Article 235 could not therefore have been used as the legal basis of the Directive, whether alone or in conjunction with other provisions, since it applies only where the Treaty has not elsewhere provided the necessary powers to legislate.

*The argument that the Directive infringes Article 100a(3)*

64. Italy refers also to Article 100a(3) of the Treaty, which requires the Commission to 'take as a base a high level of protection' in its proposals based on Article 100a 'concerning health, safety, environmental protection and consumer protection'. Italy submits that Article 100a cannot be the legal basis for a harmonising measure in a field involving fundamental interests such as health and the environment unless the contents of the proposal conform to Article 100a(3). It is clear from recital 14 in the preamble to the Directive that the Community legislature recognised the impact on health and the environment of the exploitation of biotechnological inventions but did not regulate those matters on the basis

that it was for Member States to do so. The conditions for Article 100a are accordingly not met.

*The argument that the Directive creates a new intellectual property right*

65. In my view the Directive does not fall within the scope of Article 100a(3). That paragraph applies to 'proposals... concerning health, safety, environmental protection and consumer protection'. A proposal for a directive on the legal protection of biotechnological inventions is not covered by that paragraph. While it is indisputable that both the conduct of research culminating in biotechnological inventions and the use to which such inventions are put may have significant implications for health, safety and environmental protection in particular, the proposed measure did not seek to regulate such research or use from the standpoint of health, safety or environmental or consumer protection (in contrast to, for example, the Community legislation on the release into the environment of genetically modified organisms [81]): indeed recital 14 expressly states that 'substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection...'.

66. The Netherlands submits that the Directive creates a specific right so that it cannot be said simply to harmonise national principles of patent law. The Directive requires Member States to protect biotechnological inventions under national patent law. A patent for biotechnological inventions is a patent on life. Biological matter, in particular living animals or plants, cannot be compared to dead matter which until a few years ago could alone be patented. The fact that biological matter can reproduce without human intervention means that protecting it by way of patents is different in kind from so protecting dead matter.

67. It seems to me, however, as submitted by the Parliament, that the patentability of living material is not an innovation introduced by the Directive but the recognition of what is actually happening in conformity with national law: the Member States have long recognised the patentability of certain inventions concerning a living material.

81 — Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, OJ 1990 L 117, p. 15.

68. The Parliament refers to patents granted for yeast in Belgium and Finland

in 1833 and 1843 respectively.[82] More recently, in Germany the Bundesgerichtshof held in 1975 that new micro-organisms *per se* were susceptible to patent protection[83] and in 1993 acknowledged the patentability of plants.[84] Patents for biotechnological inventions involving transgenic animals have, as already mentioned, been granted in France and Italy in 1991 and 1996 respectively.[85] Numerous European patents for biotechnological inventions have been granted since the early 1980s and recognised in the Member States to which they extend.[86]

69. Moreover the Budapest Treaty on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, which was signed in 1977 and which came into force in 1980,[87] sought to address the problem of providing, with regard to applications for patents for living organisms such as yeasts and other self-replicating organisms, a written description in sufficient detail to satisfy the requirement in most patent law systems for sufficiency of disclosure. That Treaty permitted a specification in a patent application to be supplemented by the deposit of a sample of the organism at an authorised depositary. Applications for such patents have thus for more than 20 years been recognised and regulated at international level.

70. The notion of a 'patent on life' furthermore appears to me to be unhelpful and unclear. As discussed above,[88] a patent does not give rights of ownership or unfettered rights to exploit. It merely entitles the patent-holder to prevent others manufacturing, using or selling the invention without his consent. The patent-holder however is not absolved from compliance with national regulatory requirements in areas such as public health, safety, animal welfare and compliance with ethical standards. The Directive explicitly recognises this in recital 14. The Directive also explicitly recognises numerous limits to patentability in line with national laws and international conventions, as will be discussed in some detail in the context of the third ground for annulment.

71. The Netherlands adds that in addition to creating a new right consisting of a patent over the living products of biotechnological processes, the Directive also creates a new right, so-called 'farmers' privilege'. That privilege, namely the right of a farmer to use for agricultural purposes

82 — See also note 36.

83 — *Bäckerhefe decision*, mentioned in K. Goldbach, H. Vogelsang-Wenke and F.-J. Zimmer, *Protection of Biotechnological Matter under European and German Law*, p. 1.

84 — *Tetraploide Kamille decision*, ibidem.

85 — See paragraph 60 above.

86 — See H.-R. Jaenichen, *The European Patent Office's Case Law on the Patentability of Biotechnology Inventions* (1993); K. Goldbach, H. Vogelsang-Wenke and F.-J. Zimmer, *Protection of Biotechnological Matter under European and German Law*; E.S. van de Graaf, *Patent Law and Modern Biotechnology* (1997).

87 — All Member States other than Luxembourg are contracting parties.

88 — See paragraph 25.

products protected by patents, is well known in the field of plant protection but not in patent law.

72. The 'farmers' privilege' enshrined in Article 11 of the Directive has two aspects.

73. First, Article 11(1) permits a farmer to use the seed saved from a crop he has grown from patented seed sold to him for agricultural use in order to grow another crop. That derogation is similar in kind to that in Article 14(1) of Council Regulation No 2100/94 on Community plant variety rights [89] (in turn based on provisions of the UPOV Convention 1961 and 1991), [90] although it is more extensive since Article 14(1) of the Regulation is limited to specified plant species of fodder plants, cereals, potatoes and oil and fibre plants. The extent and conditions of the derogation are to correspond to those under Article 14 of the Regulation, which provides in particular that farmers other than small farmers are to pay 'an equitable remuneration' to the holder.

74. Second, Article 11(2) provides an analogous privilege for breeding livestock. In other words, a farmer may use for an agricultural purpose (but not for commercial reproduction) patented breeding stock 'or other animal reproductive material' which he has bought. According to the explanatory memorandum in the Commission's proposal for the Directive, [91] the derogation authorises farmers 'to use the protected livestock for breeding purposes on their own farms, in order to replenish their numbers'. Article 11(3) provides that the extent and the conditions of the derogation are to be determined at national level.

75. In my view it is clear that Article 11 does not create a new right since it is solely concerned with limiting the scope of protection conferred by a patent granted pursuant to the Directive. For further discussion of the protection from which Article 11 derogates, and the rationale for that protection, see the discussion of Articles 8 and 9 in paragraph 121 et seq. below.

76. I accordingly conclude that the argument that the Directive was incorrectly based on Article 100a and should therefore be annulled must be rejected.

89 — OJ 1994 L 227, p. 1.

90 — The International Convention for the protection of new varieties of plants (UPOV being the acronym for Union internationale pour la protection des obtentions végétales, the French name of the Union established by the Convention).

91 — See note 18.

**The argument as to subsidiarity**

77. Article 3b of the EC Treaty (now Article 5 EC) provides:

'The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein.

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, 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.

Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty.'

78. Article 190 of the EC Treaty (now Article 253 EC) provides:

'Regulations, directives and decisions adopted jointly by the European Parliament and the Council... shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty.'

79. The Netherlands' principal submission is that the Directive infringes the second paragraph of Article 3b. It refers to the points it made in the context of the first head (legal basis), which in its view refute any argument that the objectives of the Directive could not be sufficiently achieved by the Member States or that those objectives could be better achieved by the Community by reason of the scale or effects of the proposed action. The recitals in the preamble simply state that the legal protection of biotechnological inventions requires clarification (recitals 4 and 9) and that differences exist in the laws and practices of the Member States which could create barriers to trade and hence impede the proper functioning of the internal market (recitals 5 and 7). Since however national patent law has been almost entirely harmonised by the European Patent Convention, the required clarification should be effected by amending that convention. The Member States are thus perfectly able to achieve that objective.

80. In the alternative, the Netherlands submits that it is not clear from the recitals

that the second paragraph of Article 3b was taken into account as required by Article 190 and *Germany* v *Parliament and Council*. [92]

81. In my view and for the reasons discussed in the context of the first head of argument (as to legal basis), it can properly be considered that the Directive was necessary in order to harmonise Member States' legislation on the patent protection of biotechnological inventions. Since — again for the reasons discussed above — such harmonisation could be effected only by the Community, and since the Community has exclusive competence in the approximation of national rules concerning the establishment and functioning of the internal market, the case for Community action has been adequately made out and the principle of subsidiarity is accordingly not infringed.

82. That the principle was respected is moreover apparent from, in particular, recitals 3, 5, 6, 7 and 9, which show that the Council and the Parliament considered the inadequacy of action at national level in the field of the legal protection of biotechnological inventions and recognised the necessity of harmonising certain principles.

92 — Case C-233/94 [1997] ECR I-2405, paragraph 28 of the judgment.

It is clear from the case-law of the Court that in such circumstances it is not necessary for the legislation to make express reference to the principle of subsidiarity. [93]

83. Finally, clarification of the law by way of amendment of the European Patent Convention would, as the defendants point out, be inappropriate, ineffective and possibly not feasible.

84. I accordingly conclude that the Directive does not infringe the principle of subsidiarity. The argument that it should be annulled on that basis must therefore be rejected.

## The argument as to legal certainty

85. The Netherlands, supported by Italy and Norway, submits that, notwithstanding the statement in its preamble that harmonisation is necessary to clarify the uncertainty regarding the protection of biotechnological inventions, [94] the Directive does not wholly resolve uncertainties concerning the patentability of biotechnological inven-

93 — See *Germany* v *Parliament and Council*, cited in note 92, paragraph 28 of the judgment.

94 — Recital 9, set out in paragraph 42 above.

tions; moreover it creates further uncertainty since the precise meaning and scope of Articles 4, 6, 8 and 9 are not clear. The Directive accordingly infringes the principle of legal certainty.

86. Before looking more closely at the substance of those arguments, the effect of uncertainty in a Community act such as a directive must be considered. The Netherlands has cited no authority for its apparent view that, if the meaning of one or two provisions of the Directive is not entirely and exhaustively clear, the Directive should be annulled; nor has Italy or Norway. Nor indeed has the Court ever to my knowledge endorsed such a principle

87. Article 249 EC (formerly Article 189 of the EC Treaty) states that a directive is to be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. Directives are thus inherently liable not to deal exhaustively with the detail of matters within their scope. While that does not of course mean that unclear drafting is appropriate, it does suggest that the mere fact that a directive confers some discretion on the Member States is not in itself a ground for invalidating it.

88. Even where a provision of a directive is open to different interpretations, as the Netherlands alleges in the present case, I do not consider that that in itself is grounds for annulment. In recent cases in which the Court has held that a Member State, in incorrectly implementing an imprecisely drafted provision of a directive, gave the provision a meaning which it was reasonably capable of bearing, there has been no suggestion that the directive (or even the provision) should be regarded as invalid merely because it was imprecise and hence open to more than one interpretation. [95] Similarly the Court in formulating the principle that only those provisions of directives which are clear and unambiguous may have direct effect has not to my knowledge suggested that all provisions not so precise and unconditional are thereby invalid.

89. I would on the other hand regard it as at least arguable that a provision in a directive which was wholly devoid of meaning, or manifestly irreconcilable with another provision thereof, may be invalid on that ground, although it does not necessarily follow in my view that the directive as a whole should thereby be annulled.

90. Against that background I will consider whether the provisions of the Directive

95 — See for example Case C-392/93 *British Telecommunications* [1996] ECR I-1631 and Joined Cases C-283/94, C-291/94 and C-292/94 *Denkavit International* [1996] ECR I-5063.

alleged to infringe the principle of legal certainty are meaningless or contradictory to that extent. The arguments focus principally on the meaning and scope of, first, Article 6 and, second, Articles 8 and 9.

...

*The arguments as to Article 6*

The relevant recitals and provisions of the Directive

91. Recitals 36, 38 and 39 in the preamble read as follows:

'(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or [from] totipotent cells of humans and animals, are obviously also excluded from patentability; [96]

(39) Whereas *ordre public* and morality correspond in particular to ethical and moral principles recognised in a Member State, respect for which is particularly important in the field of bio-

96 — See paragraph 111 below for an explanation of some of the terms used in this recital.

technology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention'.

92. Article 6 of the Directive provides:

'(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

(2) On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.' [97]

93. The Netherlands and Italy put forward four arguments to the effect that Article 6 infringes the principle of legal certainty. I propose to deal separately with each of those arguments.

Are *ordre public* and morality sufficiently clear concepts?

94. First, it is argued that Article 6 gives insufficient guidance and the principles

97 — The germ line is the group of cells which give rise to the reproductive cells. Modifications to the germ line may thus be passed on to offspring.

mentioned in the recitals for determining whether there is an infringement of *ordre public* or morality are general and equivocal. According to recital 39, the patent offices and courts must turn to the ethical and moral principles recognised in a Member State to supplement the standard legal examinations under patent law. It is therefore inevitable that Article 6 will be interpreted and applied divergently.

95. I would note at the outset that the concepts of *ordre public* and morality have a long and distinguished history as criteria for the lawfulness of the grant or exercise of intellectual property rights. In relation to trade marks, for example, Article 6 *quinquies* (A)(3) of the Paris Convention, dating from the 1911 Washington revision, provides for an exception to the general prohibition on denying registration or invalidating a trade mark where it is 'contrary to morality or public order'. In relation to patents, Article 6(1) of the Directive is, as indicated above, [98] to essentially similar effect as Article 53(a) of the European Patent Convention, although the Convention also prohibits the patenting of inventions the *publication* of which would be contrary to *ordre public* or morality. [99] Article 53 itself reproduces almost verbatim Article 2 of the Strasbourg Convention of 1963, [100] although that provision is optional ('The Contracting States shall not be bound to provide for the grant of patents in respect of...'). Article 27(2) of the TRIPs Agreement is also in similar terms, although again it is permissive rather than mandatory. [101] Provisions such as Article 6(1) have been described as 'a well-known feature of patent law'. [102]

96. Community intellectual property legislation continues this pattern. The Community Trade Mark Regulation [103] and the Trade Marks Directive [104] both provide for the refusal of registration or invalidity of a mark which is 'contrary to public policy or to accepted principles of morality' ('contraire à l'ordre public ou aux bonnes moeurs'). [105] The Community Plant Variety Rights Regulation [106] provides that there is an impediment to the designation of a variety denomination where 'it is liable to give offence in one of the Member States or is contrary to public policy' ('est susceptible de contrevenir aux bonnes moeurs dans un

98 — See paragraph 22.

99 — It appears however that the Standing Advisory Committee before the European Patent Office proposed in September 1998 that Article 53(a) should be modified so as to refer to exploitation only: see Deryck Beyleveld, 'Why Recital 26 of the EC Directive on the Legal Protection of Biotechnological Inventions Should Be Implemented in National Law' [2000] I.P.Q. 1.

100 — Cited in note 25.

101 — Presumably to accommodate the US and Japan, where as indicated (note 44) there is apparently no general ethical exclusion from patentability.

102 — M. Van Empel, *The Granting of European Patents* (1975), p. 68, citing an international survey of 10 European countries published in GRUR Int. 1960, p. 105.

103 — Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark, OJ 1994 L 11, p. 1.

104 — Cited in note 66.

105 — Article 7(1)(f) of the Regulation and Article 3(1)(f) of the Directive. It may be noted that in his Opinion delivered on 23 January 2001 in Case C-299/99 *Philips Electronics*, at paragraph 18, Advocate General Ruiz-Jarabo Colomer gave as an example of a trade mark registration of which would be barred because it was contrary to public policy the mark 'Babykiller' for a pharmaceutical abortifacient.

106 — Cited in note 89.

des États membres ou est contraire à l'ordre public'). [107] Directive 98/71 on the legal protection of designs [108] provides that a design right shall not subsist in a design which is contrary to public policy or to accepted principles of morality ('contraire à l'ordre public ou à la moralité publique'). [109] The amended proposal for a European Parliament and Council Directive approximating the legal arrangements for the protection of inventions by utility model [110] provides that utility models shall not be granted in respect of inventions the exploitation of which would be contrary to public policy or morality ('contraire à l'ordre public ou aux bonnes moeurs'). [111]

97. The concept of *ordre public* in particular also has wider significance in Community law. It is for example used in the French text of the Treaty, although it is usually rendered 'public policy' in English. [112] Articles 30, 39(3), 46(1) and 58(1)(b) (formerly Articles 36, 48(3), 56(1) and 73d(1)(b)) all refer (as grounds for permitted restrictions of the free movement of goods, the freedom of movement of workers, the freedom of establishment and the free movement of capital respectively) to *ordre public* ('public policy' in the English). The Court has recognised that the particular circumstances justifying recourse to the concept of public policy may vary from one country to another and from one period to another and that it is therefore necessary to allow the competent national authorities an area of discretion within the limits imposed by the Treaty. [113]

98. The Community legislature has also resorted to the concept of *ordre public* in numerous harmonising measures, thus apparently seeing no contradiction in conferring a degree of discretion on national authorities in an area subject to harmonisation. [114]

107 — Article 63(3)(e).

108 — Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998, OJ 1998 L 289, p. 28.

109 — Article 8.

110 — OJ 2000 C 248E, p. 56.

111 — Article 4(a).

112 — See the Opinion of Advocate General Warner in Case 30/77 *Bouchereau* [1977] ECR 1999, pages 2023 to 2026, for a discussion of the concepts of public policy and *ordre public*.

113 — Case 41/74 *Van Duyn* [1974] ECR 1337, paragraph 18 of the judgment.

114 — Article 11(2)(b) of First Council Directive 68/151/EEC of 9 March 1968 on co-ordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, with a view to making such safeguards equivalent throughout the Community, OJ English Special Edition 1968 (I), p. 41 (translated as public policy); Article 10(2)(a) of Council Directive 89/592/EEC of 13 November 1989 coordinating regulations on insider dealing, OJ 1989 L 334, p. 30 (public policy); Article 14(5) of Council Directive 90/619/EEC of 8 November 1990 on the coordination of laws, regulations and administrative provisions relating to direct life assurance, laying down provisions to facilitate the effective exercise of freedom to provide services and amending Directive 79/267/EEC, OJ 1990 L 330, p. 50 (public policy); Article 5(b) of Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons, OJ 1991 L 256, p. 51 (public order); Article 15(6) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ 1993 L 169, p. 1 (public policy); Article 6(2) of Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorisations for the prospection, exploration and production of hydrocarbons, OJ 1994 L 164, p. 3 (public safety); and Article 9(7) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ 1998 L 204, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ 1998 L 217, p. 18 (public policy).

99. The concept of 'bonnes moeurs' seems not to feature significantly in Community law apart from the measures of Community intellectual property legislation mentioned above. However it appears to be used interchangeably with 'moralité publique' in those measures so can perhaps be regarded as synonymous. Article 30 of the Treaty includes 'moralité publique' ('public morality') among the permitted grounds for derogating from the free movement of goods. The Court considered the phrase in *Henn and Darby* [115] and *Conegate*. [116] In the former, the Court ruled that it was for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory. [117] The Court confirmed that principle in *Conegate*, although ruling that on the facts the derogation was not applicable.

100. Thus the statement in recital 39 of the Directive that '*ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State' closely reflects the Court's interpretation and application of those concepts in the context of the Treaty. It cannot therefore in my view be argued that the approach of the Directive infringes the principle of legal certainty.

101. The application by national authorities of the concepts of *ordre public* and morality, however, will always be subject to review by the Court: Member States do not have an unlimited discretion to determine their scope. The Court has stated that 'recourse by a national authority to the concept of public policy presupposes, in any event, the existence, in addition to the perturbation of the social order which any infringement of the law involves, of a genuine and sufficiently serious threat to the requirements of public policy affecting one of the fundamental interests of society'. [118] That statement clearly demonstrates that the Court's approach is essentially similar to that of the European Patent Office, whose guidelines for substantive examination state that the purpose of the *ordre public* and morality provision is 'to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour...'. [119] National patent authorities which have been acting in the light of those guidelines since the European Patent Convention came into force in their Member State should accordingly experience no conflict once the Directive is in force.

102. It may be added that the discretion of a Member State to determine the scope of the concept of public morality in accordance with its own scale of values, so

115 — Case 34/79 [1979] ECR 3795.

116 — Case 121/85 [1986] ECR 1007.

117 — Paragraph 15 of the judgment. See further the Opinion of Advocate General Warner.

118 — *Bouchereau*, cited in note 112, paragraph 35 of the judgment.

119 — Guidelines for examination in the European Patent Office, as last amended in February 2001, Part C, Chapter IV, paragraph 3.1.

defined by the Court more than 20 years ago, [120] should perhaps now be read with some caution. In this area, as in many others, common standards evolve over the years. It may be that the ethical dimension of some of the basic issues within the scope of the Directive is now more appropriately regarded as governed by common standards. That was clearly the view of Technical Board of Appeal 3.3.4 of the European Patent Office in 1995, when it stated in *Plant Genetic Systems* that the concept of morality 'is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation.' [121] The fact that some ethical issues may be more appropriately evaluated in the context of the culture of a particular Member State and others are susceptible to a common standard does not however in my view preclude — either here or elsewhere — a degree of harmonisation.

What is the meaning and purpose of the proviso in Article 6(1)?

103. Second, the Netherlands and Italy submit that the meaning and purpose of the proviso in Article 6(1), which states that exploitation of an invention shall not be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation, are not clear. Moreover, the statement in recital 14 [122] that 'a patent for invention does not authorise the holder to implement that invention' is contrary to the fundamental principles of national and international patent law according to which the grant of a patent confers on the holder the exclusive right commercially to exploit the invention; furthermore, if it were correct, it would be unnecessary to exclude the patentability of inventions whose commercial exploitation was contrary to *ordre public* and morality.

104. The proviso appears in both Article 53(a) of the European Patent Convention and Article 2 of the 1963 Strasbourg Convention. [123] It pre-dates both those instruments, however, being drawn from Article 4 *quater* of the Paris Convention. That provision, which was added by the 1958 Conference of Revision at Lisbon, states:

'The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or a product obtained by means of a

120 — In *Henn and Darby*, cited in note 115.

121 — T 356/93 *Plant Genetic Systems/Plant cells* [1995] EPOR 357, paragraph 6 of the decision.

122 — Set out in paragraph 42 above.

123 — Article 27(2) of the TRIPs Agreement contains a similar proviso.

patented process is subject to restrictions or limitations resulting from the domestic law'.

105. The Bureau international de la propriété intellectuelle (the predecessor of the World Intellectual Property Organisation) has explained in a publication [124] that the reason for that provision is that restrictions or limitations may be temporary in nature so that the patent will acquire value once they have been removed. Moreover the patented invention so restricted may be the basis for further patents which do not fall within the restrictions: there is in that case no reason to deprive the holder of the first patent of licence-fees etc. to which the link between the two inventions might entitle him.

106. It is moreover not correct to assert that it would be purposeless to grant a patent for an invention the exploitation of which is prohibited. As suggested above, the inventor may wish to obtain protection in anticipation of a change in the regulatory structure enabling him to exploit his invention in the future. A good topical example is genetically modified organisms — there is a general moratorium on the use of these in the European Union at the moment, but it will not necessarily be indefinite. Similarly at national level an inventor may anticipate a change of government. Alternatively, an inventor may wish to manufacture an invention in a Member State where the exploitation (but not the manufacture) of the invention is prohibited, with a view to exporting it to States in which its exploitation is not prohibited.

107. Accordingly I do not accept that the proviso in Article 6(1) is either unclear in itself or incompatible with the statement in recital 14. Nor do I accept that that statement is contrary to the general principles of patent law: although it is correct that the grant of a patent confers the exclusive right to exploit the invention, that right is, as discussed above, [125] to be exercised in accordance with the applicable national laws and regulations. The grant of the patent thus in itself confers no absolute, positive right to exploit, but merely the right to prevent others from exploiting the invention in the territory where the patent is recognised.

Does *ordre public* encompass prejudice to the environment?

108. Third, the Netherlands and Italy refer to recital 36, which notes that the TRIPs Agreement recognises in the context of *ordre public* and morality the grounds of protection of human, animal or plant life or

124 — Bureau international de la propriété intellectuelle, *Convention de Paris — La protection de la propriété industrielle de 1883 à 1983* (1983).

125 — See paragraph 25 above.

health and the avoidance of serious prejudice to the environment. That raises the question whether, for the purpose of Article 6(1), serious prejudice to the environment, or the risk thereof, may fall within the concept of *ordre public*.

What is the status of recital 38?

109. I have already discussed in general terms the scope of the *ordre public* exception. Preservation of the environment must be regarded in the present state of Community law as one of the fundamental interests of society. That was recognised by the Court as long ago as 1988 in *Commission* v *Denmark* [126] and is now enshrined in Article 2 of the Treaty which includes the promotion of 'a high level of protection and improvement of the quality of the environment' among the Community's tasks. The 'fundamental interests of society' referred to by the Court in *Bouchereau* [127] must to my mind now be understood as extending to the environment. A genuine and sufficiently serious threat to the environment would thus fall squarely within the concept of *ordre public*; [128] there is accordingly no incompatibility between recital 36 and Article 6(1).

110. Finally, the Netherlands states that, although Article 6(2) lists examples of inventions to be considered unpatentable in accordance with Article 6(1), that list does not include (and the Directive does not otherwise provide for) the important exception to patentability spelt out in the last phrase of recital 38: 'processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or [from] totipotent cells of humans and animals, are obviously also excluded from patentability'. The Netherlands thus appears to object to the fact that an exception mentioned in a recital is not reflected in the body of the Directive.

111. It appears to me, however, as indicated by the Parliament, that that exception falls within the exclusion from patentability of 'processes for modifying the germ line genetic identity of human beings' in Article 6(2)(b). A chimera is an organism or recombinant DNA molecule created by joining DNA fragments from two or more different organisms. A germ cell is a cell destined to become a sperm or an egg. A

126 — Case 302/86 [1988] ECR 4607, paragraph 8 of the judgment (referring further back, to Case 240/83 *Association de Défense des Brûleurs d'Huiles Usagées* [1985] ECR 531).

127 — Cited in note 112. See paragraph 101 above.

128 — I would mention that that is also the understanding of the European Patent Office: see the decisions of Technical Board of Appeal 3.3.2 in T 19/90 *Harvard/Onco-mouse* [1990] EPOR 501 and Technical Board of Appeal 3.3.4 in *Plant Genetic Systems*, cited in note 121.

totipotent cell is a cell having unlimited capability. [129] The production of chimeras from germ cells or from totipotent cells of humans and animals will inevitably modify the germ line genetic identity of human beings.

112. Even if that were not so, I cannot see that a legislative measure should be annulled for lack of legal certainty merely because an example of conduct excluded from the scope of that measure appears in its preamble but not in its substantive provisions. [130] It is not moreover an unprecedented legislative technique to give an illustrative, non-exhaustive list of examples of situations where an *ordre public* exception will apply: see for example Article 9(7) of Directive 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations [131] as amended by Directive 98/48 [132] and Article 3(4)(a)(i) of the Directive on electronic commerce. [133]

129 — A fertilised human egg is for example totipotent for the first few days and cycles of cell division after fertilisation: each of the cells into which it divides has the potential to develop into a fetus. After several such cycles however the cells begin to specialise; some will form the placenta, others will form the various tissues of the human body. From that point on no one cell can form an organism (since either the placenta or the embryo will not develop).

130 — See by analogy Joined Cases C-68/94 and C-30/95 *France and others* v *Commission* [1998] ECR I-1375, paragraphs 176 and 177 of the judgment.

131 — Cited in note 114.

132 — Cited in note 114.

133 — Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, OJ 2000 L 178, p. 1.

*The argument as to plant and animal varieties*

The relevant recitals and provisions of the Directive

113. Recitals 31 and 32 in the preamble read as follows:

'(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;

(32) Whereas if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process'.

114. Article 4(1) and (2) provides:

'1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.'

115. 'Plant variety' is defined for the purpose of the Directive [134] by reference to the definition in Article 5 of Regulation No 2100/94. [135]

116. Article 8 provides:

'1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.'

117. Article 9 provides:

'The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.'

134 — By Article 2(3).
135 — Cited in note 89.

118. In the second argument as to legal certainty, the Netherlands, Italy and Norway refer to several aspects of the provisions of the Directive concerning plant and animal varieties whose meaning and effect are allegedly unclear. I propose to deal separately with each of those points.

The argument as to Articles 8 and 9

119. First, the Netherlands and Norway submit that it is not clear whether plant varieties are in all circumstances excluded from patentability. Article 4(1)(a) provides that plant and animal varieties are not patentable. However, according to Articles 8 and 9 a patent may be obtained for a biotechnological process and its products, even plants and animals. If that process creates a new variety, the protection conferred by the patent will apparently extend to that variety. Moreover, if such a process leads to a new plant variety covered by a plant variety right there may be a conflict between the holders of the patent and of the plant variety right which cannot be wholly resolved by the system of cross-licences under Article 12.

120. In my view there is no conflict between Article 4(1)(a) on the one hand and Articles 8 and 9 on the other.

121. A patent for a product normally gives the holder the exclusive right to manufacture that product (subject to compliance with applicable laws and regulations). In the case of patented material which is capable of reproducing itself, the value of the patent would clearly be eroded if it did not extend to future generations of such material. For example, if the purchaser of patented seeds were able to use the seeds produced by the crop grown from the purchased seeds, the value of that patent would be much reduced. Article 8(1) accordingly states that in such cases the protection conferred by the original patent extends to future generations of biological material derived through propagation or multiplication. Recital 46 expresses that principle in terms of the patent-holder's entitlement 'to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself'. (With regard to seeds, as discussed above [136] Article 11(1) derogates from that protection in prescribed circumstances and for a fee.)

122. Article 8(2) similarly adapts a well-known principle of traditional patent law to the exigencies of biotechnological inven-

136 — See paragraph 73.

tions. Where the subject-matter of a patent is a process, the protection conferred by the patent extends to the products directly obtained by such a process. That principle has been incorporated in international patent legislation since at least 1958, when Article 5 *quater* was inserted into the Paris Convention. [137] It finds expression in Article 64(2) of the European Patent Convention, which provides:

'If the subject-matter of a European patent is a process, the protection conferred by the patent shall extend to products directly obtained by such process.'

123. If the products so obtained are themselves capable of replication, the problem discussed in paragraph 121 will arise. For example, a patented process may result in the production of a micro-organism which can be cloned. If such material could be freely propagated by a purchaser, the value of the process patent would be nullified. Article 8(2) accordingly makes it clear that the protection conferred on biological material directly obtained by a patented process extends to future generations of that material.

124. Article 9 caters for the situation where a patent confers protection on a product containing or consisting of genetic information, such as a particular DNA sequence, or a particular gene. It extends the protection conferred by such a patent to all material, subject to the exception in Article 5(1), [138] in which the product is incorporated and in which the genetic information is contained and performs its function. Thus where the DNA sequence or gene is incorporated into a host micro-organism which may be multiplied, the patent protection enjoyed by it will extend to that micro-organism.

125. The Netherlands and Norway argue that, notwithstanding the exclusion from patentability of plant varieties in Article 4(1)(a), a plant variety may benefit from patent protection by virtue of Articles 8 and 9.

126. That proposition is to my mind based on an incorrect analysis of the position: it fails to distinguish the concept of patentability from the concept of the protection conferred by a patent. Both concepts may of course be relevant to a single situation: thus where, for example, a patented gene which confers resistance to herbicides is incorporated into a plant variety other than by or with the consent of the patent-holder,

137 — 'When a product is imported into a country of the [Paris] Union [for international protection of industrial property] where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country.'

138 — 'The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.'

that use of the gene will infringe the patent. If the original patent for the gene did not protect against such use, it would clearly be of very little value. That does not mean, however, that the plant variety will itself be patentable. An example from the field of traditional technology may help to make this clear. Historically, many countries prohibited the patenting of pharmaceutical products. If an unpatentable pharmaceutical product were manufactured which incorporated a specific chemical compound which had been patented, clearly that patent would be infringed by the manufacture of the pharmaceutical product, notwithstanding that the latter product could not itself benefit from patent protection.

127. Articles 8 and 9 thus do not mean that plant varieties will be patentable *per se*. A direct conflict between the holder of a patent for a given plant variety and the holder of a plant variety right for that variety cannot therefore arise. What may frequently happen however is that a plant breeder will wish to purchase or use a plant variety right in circumstances where that purchase or use will infringe an existing patent, for example on a gene incorporated into that plant variety. Article 12 of the Directive provides for a system of compulsory cross-licences [139] on reasonable terms where in such circumstances the holder of the plant variety right has applied unsuccessfully to the patent-holder for a licence and where the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent. [140]

128. There is thus no conflict between Article 4(1)(a) on the one hand and Articles 8 and 9 on the other.

The argument that 'animal varieties' is not defined

129. The Netherlands objects that the Directive nowhere defines the term 'animal varieties', used in Article 4(1)(a). The term 'plant varieties', also used in that article, is by contrast defined in Article 2(3). The scope of the exception for animals is accordingly unclear.

130. The exclusions from patentability in Article 4(1)(a) of the Directive echo those in Article 53(b) of the European Patent Convention which are in turn based on Article 2(b) of the Strasbourg Convention.

139 — So called because the article provides also for mirror-image licences in favour of a patent-holder who cannot exploit the patent without infringing a plant variety right.

140 — Article 12(3).

That context does not in this case help with the interpretation of the terms used; one must turn therefore to the terms themselves.

All the other language versions of the Directive use a word meaning 'breed', which is consistent with the above definition. Understood in that way, the concept of animal variety is in my view not ambiguous.

The arguments as to recitals 31 and 32 and Article 4(1)(a) and 4(2)

131. Admittedly, there is no generally recognised taxonomic definition for 'variety' as there is for 'species' or 'genus', [141] although it may be noted that the *Shorter Oxford English Dictionary* [142] gives as the biological definition of 'variety':

132. The Netherlands, supported by Norway, puts forward two arguments to the effect that the above provisions are contradictory and hence infringe the principle of legal certainty.

'A taxonomical grouping ranking next below a sub-species [143] (where present) or species, whose members differ from others of the same species or sub-species in minor but permanent or heritable characters: the organisms which compose such a grouping'.

133. First, recital 31 states that a plant grouping which is characterised by a particular gene is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants. In the text of the Directive however exclusion from patentability is not linked to the possibility of obtaining a plant variety right. Moreover recital 32 states that an invention which genetically modifies a plant variety and by which a new plant variety is obtained will still be excluded from patentability, which contradicts reci-

141 — European Patent Office Technical Board of Appeal 3.3.2 in *Lubrizol/Hybrid plants* [1990] EPOR 173, paragraph 12.

142 — 1993 edition.

143 — 'Sub-species' is defined as a 'morphologically [i.e. as to form] distinct sub-division of a species, especially one geographically or ecologically (though not usually genetically) isolated from other such sub-divisions'.

tal 31. However, recital 32 is not logical, since the appearance of a new plant variety must be irrelevant from the point of view of patentability: no patent may be obtained for a plant variety as such.

134. Second, Article 4 is also illogical: Article 4(1)(a) excludes from patentability plant and animal varieties in the plural while under Article 4(2) only inventions concerning one single variety are unpatentable. It is unthinkable in scientific terms that an invention should be technically applicable to one plant or animal variety alone: any invention linked to a genetic modification of a plant or animal will be applicable to several varieties. Article 4(2) is thus meaningless.

135. As a preliminary point, it is useful to mention the reasons underlying the exclusion of plant and animal varieties from patentability in the Directive, which is in the same terms as exclusions in the European Patent Convention [144] and the Strasbourg Convention [145] (although in the Strasbourg Convention the exclusion is expressed as an option [146]).

144 — Article 53(b).

145 — Cited in note 25, Article 2(b).

146 — For a discussion of the reasons for that difference, and the background in general to the exclusions in the two Conventions, see the decision of the Enlarged Board of Appeal of the European Patent Office in G01/98 *Novartis/Transgenic plant* [2000] EPOR 303, paragraphs 3.4 to 3.7.

136. In 1961, and hence even before the Strasbourg Convention was signed, the majority of the States which would subsequently sign the two later conventions signed the UPOV Convention. [147] The UPOV Convention in its original version provided that members could confer either special plant variety protection or patent protection (in either case under national law) on plant varieties within the scope of the Convention, but not both types of protection. Article 2(b) of the Strasbourg Convention and Article 53(b) of the later European Patent Convention exclude patent protection for plant varieties in recognition of this internationally accepted approach. [148]

137. It is helpful to bear in mind that, at the time the Directive was being drafted and going through the legislative process, the scope of the exception for plant varieties in Article 53(b) was unclear.

138. In February 1995 Technical Board of Appeal 3.3.4 of the European Patent Office had delivered a decision [149] widely interpreted as holding — contrary to earlier case-law — that a claim embracing plant varieties within its subject-matter was not allowable. In November 1995 the Enlarged

147 — See note 90.

148 — The prohibition against parallel protection was removed in the 1991 revision of the UPOV Convention.

149 — *Plant Genetic Systems*, cited in note 121.

Board of Appeal stated [150] that, correctly interpreted, that decision had held that plants grown from cells into which a gene sequence conferring resistance to herbicides had been inserted were as a result of that genetic modification a 'plant variety' within the meaning of Article 53(b).

139. Clearly that ruling, the effect of which was that any genetically modified plant was regarded as a plant variety and hence unpatentable, would have seriously undermined one of the principal objectives of the Directive. The Council and the Parliament have confirmed in their written observations to the Court that that case-law of the European Patent Office explains the wording of the relevant provisions of the Directive, which were drafted so as to ensure that they did not lead to the same result. Recital 31 states that a plant grouping characterised by a particular gene is not covered by the protection of new varieties even if it comprises new varieties. That situation however must be distinguished from an invention which consists only in genetically modifying a particular plant variety which itself results in a new variety: in such a case, recital 32 states that the exception to patentability will apply. Article 4(2) in effect reverses the decision in *Plant Genetic Systems*: an invention — such as the genetic modification of a plant so as to increase its resistance to a herbicide — may be patented if its technical feasibility is not confined to a particular variety, or to put it another way, it will not be excluded from patentability solely because the claim encompasses plant groupings which embrace more than one variety.

140. It may be noted that the above interpretation of recitals 31 and 32 and Article 4(2) is in accordance with the current case-law of the European Patent Office following the decision in December 1999 of the Enlarged Board of Appeal in the *Novartis* case. [151]

141. I accordingly conclude that all the arguments to the effect that the Directive should be annulled on the ground that it infringes the principle of legal certainty should be rejected.

**The argument as to the infringement of international obligations**

142. The Netherlands submits that, in adopting the Directive, the Parliament and Council infringed Article 228(7) of the EC

150 — G03/95 *Plant Genetic Systems/Plant cells*, decision of 27 November 1995.

151 — Cited in note 146.

Treaty (now Article 300(7) EC) since the Directive is incompatible with various international obligations.

143. Article 228 is concerned with agreements concluded between the Community and one or more States or international organisations. Article 228(7) provides:

'Agreements concluded under the conditions set out in this Article shall be binding on the institutions of the Community and on Member States.'

144. The international obligations invoked by the Netherlands arise under the TRIPs Agreement, the Agreement on Technical Barriers to Trade, the European Patent Convention and the Convention on Biological Diversity.

145. The Council submits as a preliminary point that the question whether a Community act is unlawful because it infringes provisions of an international agreement to which the Community is a party arises only if those provisions have direct effect. [152] The Council considers that the provisions of the TRIPs Agreement, the Agreement on Technical Barriers to Trade and the Convention on Biological Diversity by their nature do not have direct effect. Their alleged infringement cannot therefore be invoked as a ground for reviewing the legality of the Directive.

146. I do not however consider that, on the assumption that the provisions of the international agreements referred to do not have direct effect, that necessarily supports the conclusion which the Council draws. In *Germany* v *Council*, [153] relied on by the Council as authority for its submission, the Court stated that it could review the lawfulness of a Community act from the point of view of international obligations (the GATT rules) which did not have direct effect if the Community intended to implement a particular obligation entered into within the framework of those rules or if the Community act expressly referred to specific provisions thereof. [154] It is that criterion rather than direct effect which seems appropriate in this context.

147. More generally, it might be thought that it is in any event desirable as a matter of policy for the Court to be able to review the legality of Community legislation in the light of treaties binding the Community. There is no other court which is in a

152 — Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraphs 103 to 111, confirmed with regard to the WTO Agreement by Case C-149/96 *Portugal* v *Council* [1999] ECR I-8395.

153 — Cited in note 152.

154 — Paragraph 111 of the judgment.

position to review Community legislation; thus if this Court is denied competence, Member States may be subject to conflicting obligations with no means of resolving them.

148. I accordingly propose to consider the substance of the Netherlands' arguments concerning the alleged infringement by the Directive of various international obligations of the Member States notwithstanding the Council's submission.

*Infringement of the TRIPs Agreement*

149. Recitals 12 and 36 in the preamble to the Directive read as follows:

'(12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)... signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;

...

(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.

150. Article 1(2) of the Directive provides:

'This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.'

151. Article 27(3)(b) of the TRIPs Agreement permits members to exclude from patentability:

'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...'.

152. The Netherlands submits that the Directive prevents Member States from choosing whether to use that option since it provides for a system of patentability which extends to plants and animals other than plant and animal varieties. The Directive is accordingly incompatible with the TRIPs Agreement.

153. It seems to me that that argument can be met without needing to discuss further whether Recitals 12 and 36 and Article 1(2) of the Directive are sufficient to confer competence on the Court to review the legality of the Directive in the light of the TRIPs Agreement.

154. The option in Article 27(3)(b) of the TRIPs Agreement allows WTO Members to exclude a wide range of subject-matter from patentability. The Community, a Member, has chosen, in Article 4(1) of the Directive, to exclude only part of that range from patentability. The Community was thereby exercising the option in accordance with Article 27(3). The fact that that option is no longer available to the Netherlands is a consequence not of any infringement of the TRIPs Agreement but of the harmonising effect of the Directive.

155. Moreover the Netherlands cannot rely on Article 1(2) of the Directive. That provision states that the Directive is to be without prejudice to Member States' obligations pursuant to the TRIPs Agreement. The Netherlands' obligations under that Agreement are however not affected by Article 4(1) of the Directive, which simply exercises a right (of option) and does not affect such obligations.

*Incompatibility with the Agreement on Technical Barriers to Trade*

156. The Netherlands submits that the Directive contains technical regulations within the meaning of the Agreement on

Technical Barriers to Trade, [155] Article 2 of which regulates the adoption of such regulations. Moreover notice of draft technical regulations must be published and notified to the Secretariat of the World Trade Organisation in accordance with Article 2.9 of the Agreement. The Netherlands is not aware that the prescribed procedure has been followed; in any event, it is not apparent from the Directive itself so that the Court cannot monitor compliance.

157. The Agreement on Technical Barriers to Trade aims to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade. [156] Article 1.3 provides that all products, including industrial and agricultural products, are to be subject to the Agreement. The Agreement requires Members to ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade [157] and imposes certain requirements of publication and notification with regard to technical regulations which may have a significant effect on trade of other Members. [158] 'Technical regulation' is defined as follows:

'Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.' [159]

158. The Agreement on Technical Barriers to Trade is, like the TRIPs Agreement, a WTO Agreement. The Directive makes no reference to it, nor is there any suggestion that the Directive is intended to implement it, within the meaning of the Court's case-law. [160] The Agreement cannot therefore in my view be invoked in proceedings for the annulment of a directive.

159. I cannot in any event see any argument to support the assertion that the Directive is a technical regulation as defined by the Agreement and hence within

155 — As far as the Community is concerned, the WTO Agreement and the other agreements concluded in that connection, including the Agreement on Technical Barriers to Trade, were approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1). Those agreements are published as annexes to the Decision; the Agreement on Technical Barriers to Trade is published in OJ 1994 L 336, p. 86. They entered into force on 1 January 1996 for the Community and its Member States.

156 — See recital five in the preamble.

157 — Article 2.2.

158 — Article 2.9.

159 — Point 1 of Annex 1.

160 — See *Germany* v *Council*, cited in note 152.

the scope of the Agreement. It does not lay down product characteristics within the meaning of the Agreement, nor does it create obstacles to international trade. I accordingly consider that the Netherlands' submission on this head should be dismissed.

*Incompatibility with the European Patent Convention*

160. Article 53(a) of the European Patent Convention provides that a European patent may not be granted in respect of inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

161. Article 6(1) of the Directive provides that inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. Article 6(2) specifies several processes and one use which are in particular to be considered unpatentable. [161]

162. The Netherlands notes that the criterion of unpatentability under the Directive is thus whether the commercial exploitation of an invention is contrary to *ordre public* or morality. The criterion under the Convention however is whether the 'publication or exploitation' of an invention is contrary to *ordre public* or morality. Moreover a national patent will have to be refused on the specific grounds mentioned in Article 6(2) of the Directive, whereas the Convention provides a more general ground. An invention which has been considered unpatentable under the Directive may thus none the less be lawful in a Member State as a European patent. The Directive and the Convention are accordingly incompatible, and Article 1(2) of the Directive is thus negated.

163. However, it is clear to me that Article 228(7) of the EC Treaty does not apply to the European Patent Convention since that Convention is not an agreement concluded by the Community. The Community is accordingly not bound by the Convention and the Directive cannot infringe it. The alleged incompatibility between the Convention and the Directive cannot therefore, even if substantiated, be a ground for annulment of the Directive.

161 — Article 6 is set out in full in paragraph 92 above.

164. In any event, any differences between the substantive requirements of the two instruments are to my mind marginal. As demonstrated in the context of the Netherlands' third ground of annulment, and in particular in discussing the scope of the *ordre public* exception, there is no reason to consider that the concept of *ordre public* falls to be interpreted differently in the Convention and in the Directive. Any risk that national courts will, when applying national law implementing the Directive, interpret the concept differently from the European Patent Office when applying the Convention is now moreover even further reduced since the entire text of the Directive has (since the present case was lodged) been incorporated in the Implementing Regulations to the Convention, which state that the Directive 'shall be used as a supplementary means of interpretation'. [162]

165. Admittedly there remains the point that the prohibition on patentability in the Convention extends to inventions whose publication would be contrary to *ordre public* and morality whereas the prohibition in the Directive does not, referring solely to commercial exploitation. [163] That difference however to my mind has no practical impact, since an invention whose publication but not whose commercialisation would be so contrary seems scarcely conceivable.

166. I accordingly consider that the Netherlands' submission on this head should be dismissed.

*Incompatibility with the Convention on Biological Diversity*

167. Recitals 55 and 56 in the preamble to the Directive state:

'(55) Whereas following Decision 93/626/EEC the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Article 3 and Article 8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;

(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that "further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and

162 — See note 65.

163 — See however note 99 above.

the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity".'

168. Article 1(2) of the Directive provides:

'This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.'

169. The Convention on Biological Diversity, signed by the Community and all the Member States on 5 June 1992 and approved by the Community on 25 October 1993, [164] seeks to ensure the sustainable conservation and use of biological diversity. [165] An important aspect 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, taking into account all rights over those resources and to technologies. [166] Norway, as a member of the European Economic Area, is also a party to the Convention.

170. Genetic resources are defined as 'genetic material of actual or potential value'. Genetic material is defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity'. Technology includes biotechnology. [167]

171. Article 3 of the Convention provides:

'States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the

164 — Cited in note 34.

165 — See the recitals in the preamble, in particular the final recital, and Article 1.

166 — Article 1.

167 — Article 2.

responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.'

172. Article 8 of the Convention lays down certain measures to be taken to encourage biological diversity in natural habitats. Paragraph (j) requires the Contracting Parties to 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity'.

173. Article 16(2) of the Convention requires the provision and/or facilitation of access to and transfer of technology, including biotechnology, to developing countries under fair and most favourable terms. The second sentence of Article 16(2) states that, in the case of biotechnology subject to patents, such access and transfer are to be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights. Article 16(5) states that patents may have an influence on implementation of the Convention and requires the Contracting Parties to ensure that such rights are supportive of and do not run counter to its objectives.

174. The Netherlands submits that the relationship between the patentability of biotechnological inventions and the obligations flowing from the Convention on Biological Diversity is unclear. In particular it is not clear to what extent the grant of a patent for a biotechnological invention obtained from, or consisting of, a biological material which is to be found exclusively in developing countries or developed by traditional methods is compatible with the obligation equitably to share the knowledge and benefits of genetic resources. Where a patent has been granted, the rights of the holder cover not only the protected biotechnological invention or material but also the products of that material. Farmers in developing countries will therefore be able to profit from that invention only after payment of dues to the patent-holder. Implementation of the Directive may accordingly involve infringing the Convention.

175. Moreover, although the Directive draws a clear distinction between inventions, which are patentable, and discoveries, which are not, there is a risk that traditional products and processes originating in developing countries may be mistakenly granted a patent even though they are discoveries rather than inventions: it is in practice difficult to determine whether living material is a discovery or an invention, precisely because not all traditional products and processes are known. In that case, the income from such patents would benefit not the developing country con-

cerned but the (Western) patent-holder. The developing country would have to launch lengthy and costly legal proceedings to challenge a patent once granted, which would conflict with the requirement in the Convention that knowledge and the benefit of genetic resources in the developing countries should be justly shared.

176. Norway submits that several aspects of the Directive are incompatible with the object and purpose of the Convention. Implementation of the Directive may thus force States to disregard provisions of the Convention. Moreover adoption of the Directive in the EEA Joint Committee will create serious problems for Norway, which will be subject to conflicting Treaty obligations. The Directive should accordingly be annulled.

177. In my view, the arguments that the Directive is incompatible with the Convention on Biological Diversity betray a failure to appreciate the respective objectives and spheres of application of the two instruments.

178. The Directive, as is clear from the analysis in the context of the earlier grounds for annulment, requires the Member States of the European Union to ensure that their national law provides patent protection for biotechnological inventions as there defined. To that effect it imposes a few highly specific obligations on the Member States in that narrow context. Patents conferred in accordance with the Directive will of course, as with all patents, be territorial in effect.

179. The Convention, in contrast, is more in the nature of a framework agreement. Having set out its objectives in Article 1, the Convention proposes a series of approaches which Contracting Parties (which as at 5 June 2001 numbered 180 States worldwide) are to adopt, in many cases only 'as far as possible and as appropriate'. [168] The scope of the Convention is rather wide; the suggested measures are rather varied and in most cases couched in general terms.

180. It is axiomatic that nothing in the Directive could require States which are not Member States of the European Union (or Contracting Parties to the Agreement on the European Economic Area) to confer patent protection on biotechnological inventions (although of course other international instruments, including the TRIPs Agreement, may have precisely that effect). Thus the approach of developing countries — where, as the Netherlands and Norway suggest, much genetic richness is concentrated — to the patent protection of biotechnological inventions remains unaffected by the Directive.

168 — Articles 5, 6(b), 7, 8, 9, 10, 11 and 14.

181. The Directive, being concerned with patents, does not seek to regulate matters outside the realm of industrial property. Again as discussed both above and below, [169] it is not for patent legislation to provide for broader matters such as monitoring the source of biological material in respect of which patent protection is sought. The Directive does not — nor can it — affect the ability of developing countries to establish controls over their genetic resources in order to prevent the unregulated plundering of such resources. At least a dozen countries have already taken such steps, in accordance with the Convention on Biological Diversity, and a similar number are currently developing controls. [170]

182. I do not understand how, as the Netherlands submits, traditional products and processes originating in developing countries may be patented in accordance with the Directive even though they are discoveries not inventions. As the Directive makes explicit, [171] in order to be patentable an invention must be new, must involve an inventive step and must be susceptible of industrial application. Those requirements, which have been part of patent legislation in one form or another since the Venetian law of 1474, [172] are not mere formalities, but are the essential conditions of patentability which must each be satisfied before a patent can be granted. Natural resources as such cannot therefore be the object of a patent.

183. In any event, nowhere does the Convention prohibit or restrict the patentability of biotechnological materials, or even of genetic resources; on the contrary, Article 16(2) of the Convention requires that access to and transfer of biotechnology subject to patents shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights.

184. I accordingly reject the arguments that the Directive and the Convention on Biological Diversity are incompatible, without therefore needing to consider what the implications of any such incompatibility would be.

169 — See paragraph 25 above and paragraphs 211-214 below.

170 — The Philippines, for example, requires bio-prospectors to obtain prior informed consent from both the government and local peoples; Costa Rica's National Institute of Biodiversity has signed an agreement with a major drug company to receive funds and share in benefits from biological materials that are commercialised; countries of the Andean Pact require bio-prospectors to meet certain conditions (Convention on Biological Diversity website).

171 — In Article 3(1), set out in paragraph 187 below.

172 — 'any new ingenious contrivance... reduced to perfection, so that it can be used and exercised'. See S.P. Ladas *Patents, Trademarks, and Related Rights — National and International Protection* (1975), pp. 6 and 7.

The argument as to fundamental rights

185. Article F(2) of the Treaty on European Union states:

'The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law.'

186. Recitals 16, 20, 21, 26 and 43 in the preamble to the Directive state:

'(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

...

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to

reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

...

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have an opportunity of expressing free and informed consent thereto, in accordance with national law;

...

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law'.

187. Article 3(1) of the Directive provides:

'For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.'

188. Article 5 provides:

'1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.'

189. The Netherlands, citing *X* v *Commission*,[173] submits that any Community act which infringes any fundamental right is unlawful. In its view, the Directive infringes fundamental rights both by commission and by omission.

190. The Netherlands submits first that Article 5(2) of the Directive provides that elements isolated from the human body are patentable. The right to human dignity is recognised by the Court as a fundamental right. The human body is the vehicle for human dignity. Making living human matter an instrument is not acceptable from the point of view of human dignity.

191. The Netherlands submits second that the Directive fails to provide for careful management of human material and for the consent of the persons concerned in two contexts.

192. First, the donor of elements isolated from the human body which are patented must at the very least have some control over the fate of his body, or a part thereof. Only in recital 26 however does the Directive mention the donor's right. Recitals have no binding legal force. The fact that there is nothing in the body of the Directive ensuring that human matter is managed carefully must be considered to be contrary to fundamental rights.

193. Second, there is no provision in the Directive for the protection of the recipient of material which has been processed or obtained by biotechnological means. A patient may thus without knowledge or consent receive such treatment. The Netherlands submits that the obligation to respect private life, medical confidence, the right to physical integrity and the protection of the right to personal information, as recognised in the case-law of the Court, may be grouped together as 'personal rights'. In the context of medical treatment, the right of patients to self-determination is in the same category. The Directive seriously and without justification infringes that right.

194. Italy supports the submissions of the Netherlands, adding that a directive which regulates a matter such as biotechnology whose effect on fundamental rights is unquestionable but which fails to provide

173 — Case C-404/92 P [1994] ECR I-4737.

the necessary guarantees that its application will protect those rights cannot be valid.

195. Thus the Netherlands considers that the Directive violates fundamental rights in two ways: it contains a provision (Article 5(2)) which is contrary to human dignity and it fails to provide for the respect of donors' right of control over donated matter and of medical patients' right of consent to treatment. It is helpful in my view to deal with these arguments separately.

196. I would note that the arguments presented to the Court on the compatibility of the Directive with fundamental rights focus on the abovementioned specific issues alone. I must therefore restrict my analysis of the alleged incompatibility of the Directive with fundamental rights to those issues.

197. There can be no doubt in my view that the rights invoked by the Netherlands are indeed fundamental rights, respect for which must be ensured in the Community legal order. The right to human dignity is perhaps the most fundamental right of all, and is now expressed in Article 1 of the Charter of Fundamental Rights of the European Union,[174] which states that human dignity is inviolable and must be respected and protected. The right to free and informed consent both of donors of elements of the human body and of recipients of medical treatment can also properly be regarded as fundamental; it is also now reflected in Article 3(2) of the EU Charter which requires in the fields of medicine and biology respect for 'the free and informed consent of the person concerned, according to procedures laid down by law'. It must be accepted that any Community instrument infringing those rights would be unlawful.

198. In my view, however, the Directive does not infringe fundamental rights as alleged by the Netherlands and Italy.

*Does Article 5(2) infringe fundamental rights?*

199. In the first place, I cannot accept the Netherlands' assertion in absolute terms that a patent for an element isolated from the human body is contrary to human dignity. That submission appears to be based on the premiss that patent protection of such an element amounts to an appropriation of part of the human body concerned. A patent however confers no rights of ownership. Moreover, the Directive provides that neither the human body itself

174 — Done at Nice, 7 December 2000, OJ 2000 C 364, p. 1.

nor the simple discovery of one of its elements may be patented. [175] As a matter of general patent law, which is made explicit in Article 3(1) of the Directive, only inventions which are new, which involve an inventive step and which are susceptible of industrial application are patentable. [176] The discovery of an element of the human body, such as a gene, thus cannot be patented; only when the gene has been isolated from its natural state by, for example, processing through purifying steps that separate it from other molecules naturally associated with it, can it be patented, and then only if its industrial application, for example the production of new drugs, is disclosed in the patent application in accordance with Article 5(3) of the Directive. The patent will therefore not cover the gene as it occurs in the human body, since genes in the body are not in the isolated and purified form which is the subject of the patent. [177]

200. Thus the maxim 'no patent on life' is something of an over-simplification.

201. None the less, circumstances in which the grant of a patent for an element isolated from the human body offends against human dignity may perhaps be imagined; moreover future developments in biotechnology may make feasible products or processes which are unimaginable now but which would similarly offend against human dignity. Such inventions would however unquestionably be unpatentable under the Directive by virtue of the exclusion from patentability in Article 6(1) of inventions whose commercial exploitation would be contrary to morality. The Directive thus provides an essential safeguard against the issue of such a patent. That safeguard is moreover so framed as to accommodate future developments: the generality of the standard ensures that it can be applied to inventions in this fast evolving field the detail of which cannot at present be foreseen. It is no doubt for that reason also that the legislature chose not to lay down in Article 6(2) an exhaustive list of examples of inventions which are to be considered unpatentable by virtue of Article 6(1). A case-by-case evaluation of patent applications in the light of moral consensus is the surest guarantee that the right to human dignity will be respected, and that is the framework established by the Directive.

202. It thus seems to me that Articles 5 and 6 of the Directive draw a careful line between cases where elements of human origin should not be regarded as patentable

175 — Article 5(1).

176 — For examples of revocation or invalidation of a patent granted for a biotechnological product or process on the ground *inter alia* that the national patent law requirements of novelty and inventive step had not been satisfied, see the judgments of the Court of Appeal (England and Wales) in *Re Genentech's Patent* [1989] RPC 147 (protein genetically engineered from human cells) and of the House of Lords (England and Wales) in *Biogen* v *Medeva* [1997] RPC 1 (DNA sequence coding for hepatitis B virus antigen).

177 — See also the decision of the European Patent Office Opposition Division in *Howard Florey/Relaxin* [1995] EPOR 541, where similar arguments based on the morality exception in Article 53(a) of the European Patent Convention were unsuccessfully adduced against the patentability of isolated DNA fragments encoding human H2-relaxin (a protein).

and those where they can properly be regarded as patentable.

203. The Directive also reflects the conclusions of the Group of Advisers to the European Commission on the ethical implications of biotechnology. In its report on the ethical aspects of patenting inventions involving elements of human origin, [178] the Group of Advisers does not recommend excluding the patentability of such inventions as a matter of principle, but considers that it should be subject to certain ethical principles, with the result that fundamental human rights are respected. Thus it says: 'Whatever is the nature of the biotechnological invention involving elements of human origin, the Directive must give sufficient guarantee so that refusal to grant a patent on an invention in so far as it infringes the rights of the person and the respect of human dignity should be legally founded.' That guarantee is to be found in the exclusion from patentability on the ground of morality in Article 6(1) of the Directive.

204. I do not therefore consider that the Directive infringes human dignity by providing that elements isolated from the human body may be patented.

178 — Opinion of 25 September 1996.

*Does the failure to provide for consent infringe fundamental rights?*

205. It is not however sufficient to say that the provisions of the Directive do not in themselves infringe fundamental rights. The complaint of the Netherlands and Italy is also that the Directive fails to contain certain provisions necessary to protect such rights and thereby infringes those rights. In particular it fails to ensure that such rights are respected when patents are initially granted for biotechnological products and processes and when such patented products and processes are subsequently exploited and used.

206. The Netherlands submits first that the Directive should provide for the donor of elements isolated from the human body which are patented to have control over the fate of his body or a part thereof.

207. Recital 26 states that, where a patent application is filed for an invention based on or using biological material of human origin, the donor of that material 'must have had an opportunity of expressing free and informed consent thereto, in accordance with national law'.

208. That recital has its origins in an amendment proposed by the Parliament

which would have inserted a new Article 8a(2) in the Directive, requiring *inter alia* that an applicant for such a patent must provide 'evidence to the patent authorities that the material has been used and the patent applied for with the voluntary and informed agreement of the person of origin...'. [179] That amendment was not accepted.

209. It is not clear from the wording of recital 26 in the various language versions whether the consent must relate to the filing of the patent application or to the taking of the material from the donor. Recital 26 therefore may not go as far as recommended by the Group of Advisers to the Commission, [180] which stated:

'The ethical principle of informed and free consent of the person from whom retrievals are performed, must be respected. This principle includes that the information of this person is complete and specific, in particular on the potential patent application on the invention which could be made from the use of this element. An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent will not fulfil the ethical requirements.'

179 — Amendment 76/rev. in the legislative resolution embodying the Parliament's opinion on the proposal for the Directive, OJ 1997 C 286, p. 87.

180 — See note 178.

210. It is of course clearly desirable that no element of human origin should be taken from a person without their consent. That principle is expressed at the forefront of the EU Charter of Fundamental Rights; [181] it is also enshrined in Chapter II of the Council of Europe Convention on human rights and biomedicine, [182] which provides that an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. [183]

211. In my view, however, although the requirement of consent to all potential uses of human material may be regarded as fundamental, patent law is not the appropriate framework for the imposition and monitoring of such a requirement. A patent, as discussed above, [184] simply confers the right to prevent others from using or otherwise exploiting the patented invention; how the grantee of the patent uses or exploits that invention is regulated not by patent law but by national law and practice governing the field concerned.

212. Moreover to make evidence of such consent a condition of granting a biotech-

181 — See paragraph 197 above.

182 — Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine signed at Oviedo on 4 April 1997; European Treaty Series No 164.

183 — The Convention has been in force since 1 December 1999, although of EU Member States only Denmark, Greece and Spain have both signed and ratified it.

184 — See paragraph 25 above.

nological patent — presumably by way of the morality principle — to my mind risks being unworkable. Biotechnological inventions may derive from research on possibly thousands of blood or tissue samples, possibly pooled and almost certainly anonymous at the time of analysis. I do not consider that it is reasonable to expect patent examiners to satisfy themselves that the chain of consent with regard to each sample is unbroken and evidenced. It is rather the responsibility of the medical or research staff taking the samples to ensure that consent is given; that responsibility, together with the form and scope of the consent, will be imposed by national regulations, codes of practice etc outside the patent arena. That approach is not inconsistent with recital 26, which refers to 'national law'. Patentability on the other hand is to be assessed only on the basis of the nature of the product or process itself, or on the ground that any commercial or industrial application would be objectionable.

213. Thus in my view the Directive is not the proper place for rules governing the consent of the donor or of the recipient of elements of human origin. Indeed such questions of consent arise more generally with regard to any use of human substances, such as transplants, organ donation, etc. That supports the view that the issues are not to be resolved by patent law, and in particular by patent law as it applies in this specific sector.

214. The Netherlands also submits that the Directive, by failing to require that a patient must consent to receiving medical treatment involving material which has been processed or obtained by biotechnological means, infringes fundamental rights. That argument is in my view misconceived. The conditions of exploitation or use of patented inventions are, as discussed above,[185] outside the scope of patent legislation, falling to be controlled by other means. That is clearly spelt out by recital 14: it is not for substantive patent law, which merely entitles the holder to prohibit third parties from exploiting his inventions for industrial and commercial purposes, to replace ethical monitoring of research or the commercial use of its results. Similarly, as the Council points out, the Directive contains no provision requiring that the recipient of biotechnologically processed matter must be informed simply because it does not and cannot seek to regulate the use or commercialisation of such matter.

215. I therefore reach the conclusion that the Directive does not, either by what it provides or by what it fails to provide, infringe, in itself, fundamental rights recognised in Community law. The possibility cannot of course be excluded that a particular application of the Directive within a Member State may infringe fundamental rights, although it contains provisions designed to avoid that consequence. But the conclusion is clear in my view that the

185 — See paragraph 25 above.

Directive does not in itself infringe fundamental rights.

The argument that the correct procedure was not followed

216. The Netherlands submits that the Directive was not properly adopted since it is based on an unlawful proposal by the Commission. It accordingly infringes the combined provisions of Articles 100a and 189b(2) of the EC Treaty or, at least, those provisions combined with Article 190 of the EC Treaty.

217. Article 189b(2) (now, after amendment, Article 251(2) EC) provides, with regard to legislation governed by that article, that the Commission is to submit a proposal to the European Parliament and the Council.

218. Article 190 (now Article 253 EC) provides:

'Regulations, directives and decisions adopted jointly by the European Parliament and the Council... shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty.'

219. The Netherlands submits that the Commission's operations are governed by the principle of collegiality. [186] That principle is based on the equal participation of the Commissioners in the adoption of decisions, from which it follows in particular that decisions should be the subject of collective deliberations and that all the members of the college of Commissioners should bear collective responsibility at political level for all decisions adopted. [187] The formal requirements for effective compliance with the principle of collegiality vary according to the nature and legal effects of the acts adopted by that institution. [188] The Commission's proposal, which was indispensable to adoption of the Directive, should have been adopted by the college in its definitive version as presented to the Parliament and Council; its text should also have been made available to all the members of the college in all the official languages when it was adopted by the Commission. Nothing in the Directive suggests that this essential procedural requirement was observed.

220. With regard to the argument as to the principle of collegiality, it appears from its reply that the Netherlands is not alleging that that principle was in fact infringed, but merely that the Commission did not verify compliance therewith, or at least that there is no trace of such verification in the preamble to the Directive.

186 — Case C-137/92 P *Commission* v *BASF* [1994] ECR I-2555, paragraph 62 of the judgment.

187 — *BASF*, paragraph 63 of the judgment.

188 — Case C-191/95 *Commission* v *Germany* [1998] ECR I-5449, paragraph 41 of the judgment.

221. As for the submission that the Commission did not verify compliance with the principle, the Commission states (and the Netherlands does not dispute) that the proposal was adopted by the Commission at its meeting of 13 December 1995; the adoption was hence unquestionably lawful.

222. As for the submission that the preamble to the Directive is silent, I would note that there is nothing in the Treaty provisions invoked by the Netherlands which supports its apparent contention that it must be stated in Community legislation that the principle of collegiality has been respected.

223. With regard to the argument that the proposal should have been made available to all the members of the college in all the official languages when it was adopted by the Commission, it must be borne in mind that a Commission proposal is not a decision taking the form of one of the acts referred to in Article 189 of the EC Treaty and is not therefore required by the Treaty to be adopted in authentic versions in all languages. I accept the Commission's submission that it would be inappropriate, and is not necessary in order to respect the principle of collegiality, to require a proposal to be adopted by the college in all languages.

224. In support of that submission, the Commission refers to Article 6 of Regulation No 1 of the Council determining the languages to be used by the European Economic Community,[189] which states that the institutions of the Community may stipulate in their rules of procedure which of the official and working languages are to be used in specific cases. In implementation of that provision, Article 4 of the Rules of Procedure of the Commission states that 'The agenda and the necessary working documents shall be circulated to the Members of the Commission within the time-limit and in the working languages prescribed by the Commission in accordance with Article 24', which latter provision requires the Commission to determine rules to give effect to the Rules of Procedure. Those implementing rules provide that the working documents relating to an agenda are to be sent to the Members of the Commission *in the languages fixed by the President taking account of the minimum needs of the members*. The proposal for the Directive was presented to the Members of the Commission in English, French and German and — as is customary — sent to the other institutions in all the official languages.

225. I would accordingly reject the argument that the Directive was not properly adopted since it was based on an unlawful proposal by the Commission.

189 — OJ, English Special Edition I (1952-58), p. 59.

## Conclusion

226. It follows, for the reasons I have given, that this action must, in my opinion, fail. But the action may not have been fruitless. It is clear, I think, that it was prompted by understandable concerns, reflecting a general awareness that the irresponsible pursuit of biotechnological research may have consequences which are ethically unacceptable. Although some of the grounds of challenge were of a purely technical character, those concerns were central. The action may not have been fruitless in that it may have shown that those concerns can and should be allayed.

227. Thus the Directive is concerned in particular with the patentability of biotechnological inventions and not with their use. Within that framework, there are adequate moral safeguards going in some respects beyond mere application of the existing criteria for patentability. The fact that the ethical criteria for patentability are not exhaustively defined, far from undermining the moral safeguard, enhances it since future developments will continue to be governed by those criteria even if not currently foreseeable. Biotechnological inventions which are contrary to human dignity consequently neither are now nor can in the future be patentable in accordance with the Directive.

228. The action moreover highlights the importance of regulating at national level the use of biotechnological material, precisely because such use, since it falls outside the parameters of patentability, is not — indeed cannot be — regulated by the Directive. In particular, adequate provision must be made for ensuring that the principle of informed consent is respected whenever material is taken from human beings which might be used for scientific or technological purposes.

229. It is not therefore the Directive itself which is objectionable as a result of what it contains or what it omits. It is of course crucial that its implementation be carefully controlled to ensure especially that the moral safeguard is fully transposed and assiduously observed. I am satisfied however that the Community legislative framework itself is not illegal.

230. In the result I am of the opinion that:

(1) The action should be dismissed;

(2) The Kingdom of the Netherlands should be ordered to pay the costs of the European Parliament and of the Council;

(3) The interveners should bear their own costs.