Court of Justice EC, 16 June 2005, Commission v Italy

PATENT LAW - BIO-TECHNOLOGY DIRECTIVE

Violation of Article 5(2) Bio-technology Directive: Italian patent law does not allow to patent elements of the human body that have been isolated

- As the Court has held in this connection, the elements of the human body are not patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent (Netherlands v Parliament and Council, cited above, paragraph 72).
- Thus, as is stated in the 20th and 21st recitals in the preamble to the Directive, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated (Netherlands v Parliament and Council, paragraph 73).
- That distinction applies to work on the sequence or partial sequence of human genes. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by Article 5(3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the dis-covery of a DNA sequence, which would not be pat-entable as such (Netherlands v Parliament and Council, paragraph 74).
- Thus, the protection envisaged by the Directive covers only the result of inventive scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application (Netherlands v Parliament and Council, paragraph 75).

Violation of Article 6(2) Bio-technology Directive: Member States have no discretion with regard to the unpatentability of the processes and uses which it sets out

- Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public (public policy) and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, Netherlands v Parliament and Council, paragraphs 37 to 39). It is apparent from the 40th recital in the preamble to the Directive that processes for cloning human beings must be excluded 'unequivocally' from patentability, since there is a consensus on this question within the Community

Violation of Article 8-11 Bio-technology Directive: protection for biological material directly obtained through patented process and any material derive through propagation or multiplication

- Thus, although it is correct, as the Italian Government submits, that Article 1bis(1)(b) of Royal Decree No 1127/39 provides that a patent on a process confers on its holder the right to prohibit third parties from using the product directly obtained from that process, the fact remains that this provision does not require, as Article 8(2) of the Directive does, that 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 is to extend to biological material directly obtained through that process and to any other biological material derived through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
- Nor, contrary to Articles 8(1) and 9 of the Directive, does Italian patent law provide that the protection con-ferred, first, by a patent on biological material and, sec-ond, by a patent on a product containing or consisting of genetic information extends, respectively, to any biological material derived from that biological mate-rial through propagation or multiplication, and to all material in which the product is incorporated and in which the genetic information performs its function.

Article 12 Breach Biotechnology Directive: compulsory license in case of interdependence between patent on biological material invention and plant variety right

- While Article 54(2) of Royal Decree No 1127/39 provides for the grant of a compulsory licence where an invention protected by a patent cannot be used without infringing the rights arising from another, prior, patent, it does not provide, as Article 12(1) and (2) of the Directive does, for the grant of such a licence in the case of interdependence be-

tween a patent on a biotechnological invention and a plant variety right. Furthermore, Article 54(2) of Royal Decree No 1127/39 does not oblige the applicant for the compulsory licence either to pay an appropriate royalty, as Article 12(1) and (2) of the Directive requires, or to have applied unsuccess-fully to the holder of the patent or of the plant variety right to obtain a contractual licence, as Article 12(3) of the Directive prescribes.

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Court of Justice EU, 16 June 2005
(A. Rosas, J.-P. Puissochet, S. von Bahr, U. Lõhmus and A. Ó Caoimh)
Judgment of the Court (Third Chamber)
16 June 2005 (*)
(Failure of a Member State to fulfil obligations – Directive 98/44/EC – Legal protection of biotechnological inventions – Admissibility – Failure to transpose – Ar ticles 3(1), 5(2), 6(2) and 8 to 12)
In Case C-456/03,
ACTION under Article 226 EC for failure to fulfil obligations, brought on 27 October 2003,
Commission of the European Communities, represented by K. Banks, acting as Agent, with an address for service in Luxembourg,
applicant,
v
Italian Republic, represented by I.M. Braguglia, acting as Agent, assisted by P. Gentili, avvocato dello Stato, with an address for service in Luxembourg,
defendant,
THE COURT (Third Chamber),
composed of A. Rosas, President of the Chamber, J.-P. Puissochet, S. von Bahr, U. Lõhmus and A. Ó Caoimh (Rapporteur), Judges,
Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: R. Grass,
having regard to the written procedure,
after hearing **the Opinion of the Advocate General at the sitting on 10 March 2005,**
the following
Judgment
1 By its application, the Commission of the European Communities requests the Court to declare that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13; 'the Directive'), the Italian Republic has failed to fulfil its obligations under Article 15 of the Directive.
Legal context
Community legislation
2 Article 1(1) of the Directive provides:
'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 this Directive.'
3 Article 3(1) of the Directive states:
'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.'
4 Article 5 of the Directive 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.'
5 Article 6 of the Directive states:
'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.'
6 Chapter II of the Directive is devoted to the scope of the protection conferred by a patent relating to a biotechnological invention. It contains the following provisions:
'Article 8
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.
Article 9
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.
Article 10
The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.
Article 11
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.'
7 Article 12 of the Directive provides:
'1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.
2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.
3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.
…'
8 Finally, Article 15 of the Directive provides:
'1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.
2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.'
National legislation
9 Article 5 of the Italian Civil Code provides:
'Acts of disposition of one's body are prohibited when they cause a permanent diminution of physical integrity or are otherwise contrary to law, public policy or morality.'
10 Article 1bis(1) of Royal Decree No 1127 of 29 June 1939 (GURI, No 189, of 14 August 1939; 'Royal Decree No 1127/39') provides:
'In particular, a patent shall confer on its holder the following exclusive rights:
(a) where the patent relates to a product, the right to prohibit third parties, without his authorisation, to produce, use, market or sell the product concerned or to import it for such purposes;
(b) where the patent relates to a process, the right to prohibit third parties, without his authorisation, to apply the process and to use, market, sell or import for such purposes the product directly obtained from the process concerned.'
11 Article 12 of Royal Decree No 1127/39 provides:
'Inventions which are new, involve an inventive step and are susceptible of industrial application shall be patentable. The following, in particular, shall not be considered to be inventions for the purposes of the preceding paragraph:
(a) discoveries, scientific theories and mathematical models;
…
The provisions of the preceding paragraph shall prevent the matters referred to therein from being patentable only in so far as the patent application or the patent relates to discoveries, theories, plans, principles, processes and programmes considered as such. Processes for the surgical or therapeutic treatment of humans or animals and diagnostic procedures used on humans and animals shall not be considered to be inventions for the purposes of the first paragraph …'
12 Article 13 of Royal Decree No 1127/39 states:
'Inventions shall not be patentable where their exploitation would be contrary to public policy or morality; however, exploitation of an invention cannot be deemed to be contrary thereto merely because it is pro-

hibited by law or administrative provision. Animal breeds and essentially biological processes for obtaining them shall also not be patentable; this provision shall not apply to microbiological processes or the product of those processes.'

13 Article 54(2) of Royal Decree No 1127/39 provides:

'A compulsory licence as referred to in paragraph 1 may also be granted

…

(b) if the invention protected by the patent cannot be used without infringing the rights arising from a patent granted on the basis of a prior application. In this case, a licence may be granted to the holder of the subsequent patent to the extent necessary for exploitation of the invention so long as the latter constitutes significant technical progress of considerable economic importance compared with the subject-matter of the prior patent. Without prejudice to Article 54bis(5), the licence thus obtained shall not be assignable separately from the invention which depends thereon. The holder of the patent on the principal invention is entitled in turn to grant of a compulsory licence, on reasonable terms, in respect of the patent on the dependent invention.'

Pre-litigation procedure

14 After establishing that the Italian Republic had not informed it of the laws, regulations and administrative provisions adopted by the Italian Republic to comply with the Directive, and in the absence of any other information from which it could conclude that those measures had been adopted, the Commission sent a letter of formal notice under Article 226 EC to that Member State on 30 November 2000, calling on it to submit its observations within a period of two months.

15 On 19 December 2002, having received no reply within the period set, the Commission issued a reasoned opinion in which it concluded that, by not adopting the provisions necessary to comply with the Directive, the Italian Republic had failed to fulfil its obligations under the Directive. The Commission called on the Italian Republic to adopt those provisions within a period of two months from receipt of the reasoned opinion.

16 The Italian authorities replied by letter of 6 February 2003. Subsequently, by letter of 10 July 2003, they indicated to the Commission that preparation of the provisions needed to transpose the Directive had reached an advanced stage.

17 Taking the view that this information was unsatisfactory, the Commission decided to bring the present action.

The action

18 It is to be observed at the outset that the Italian Government, while not expressly raising a plea of inadmissibility, puts forward a number of objections of a procedural nature which may affect the admissibility of the action. These objections relating to admissibility should accordingly be examined first, before assessing the merits of the action.

Admissibility

19 The Italian Government contends that, given the wording of Article 1 of the Directive, according to which the Member States must adapt their national patent law 'if necessary' – an obligation which presupposes that there is already a high degree of protection and of harmonisation of national legislation – the Commission could not in its application merely record the formal lack of transposition of the Directive within the period laid down, but had the task, at this stage of the proceedings, of adducing the necessary specific proof that the domestic law in force failed wholly or partially to comply with the Directive. The particulars put forward in this regard by the Commission in its reply were submitted out of time and consequently cannot be taken into account.

20 The Commission submits that Article 1 of the Directive does not impose any particular burden of proof on it when it complains that a Member State has not enacted any implementing measures. Here, the Italian authorities never stated during the pre-litigation procedure that domestic law complied with the Directive. Quite to the contrary, by indicating that an implementing law was in the course of being drawn up, they admitted, at least implicitly, that specific provisions had to be adopted in order to transpose the Directive.

21 It must be stated that the Italian Government's arguments in this respect in effect contest on two counts the proper conduct of the infringement procedure initiated by the Commission and, therefore, the admissibility of the present action.

22 First, by pointing out that the application merely records the absence of any transposition of the Directive and does not show in what way the domestic law in force does not already comply with the Directive, the Italian Government complains not only that the Commission has not proved the substance of the failure to fulfil obligations but also that it did not place before the Court in the application the particulars needed to establish that that failure has occurred. Second, by objecting to the possibility of this material being put forward for the first time in the reply, the Italian Government complains that the Commission has put forward pleas out of time.

23 So far as concerns the fairst of those contentions, in accordance with the case-law an application must, by virtue of Article 21 of the Statute of the Court of Justice and Article 38(1)(c) of the Rules of Procedure of the Court of Justice, contain inter alia a brief statement of the pleas in law on which the application is based. Accordingly, in any application lodged under Article 226 EC, the Commission must indicate the specific complaints upon which the Court is called to rule and, at the very least in summary form, the legal and factual particulars on which those complaints are based (see, inter alia, Case C-347/88 Commission v Greece [1990] ECR I-4747, paragraph 28). 24 The application lodged by the Commission, according to which it essentially alleges that the Italian Republic has not adopted any measure necessary for transposing the Directive, contains a clear statement of this complaint and of the legal and factual particulars on which it is based.

25 Admittedly, it is common ground that in that pleading the Commission did not seek to show in what way the Italian law in force did not comply with the Directive.
26 However, it should be remembered that while, in proceedings under Article 226 EC for failure to fulfil obligations, it is indeed incumbent upon the Commission, which has the burden of proving the allegation that the obligation has not been fulfilled, to place before the Court the information needed to enable the Court to establish that it has not been fulfilled, in doing which the Commission may not rely on any presumption, it is also for the Member States, under Article 10 EC, to facilitate the achievement of the Commission's tasks, which consist in particular, pursuant to Article 211 EC, in ensuring that the provisions of the EC Treaty and the measures taken by the institutions pursuant thereto are applied (see, inter alia, Case 96/81 Commission v Netherlands [1982] ECR 1791, paragraphs 6 and 7, and Case C-408/97 Commission v Netherlands [2000] ECR I-6417, paragraphs 15 and 16). It is for that reason that Article 15 of the Directive, like other directives, imposes upon the Member States an obligation to provide information.
27 The information which the Member States are thus obliged to supply to the Commission must be clear and precise. It must indicate unequivocally the laws, regulations and administrative provisions by means of which the Member State considers that it has satisfied the various requirements imposed on it by the directive. In the absence of such information, the Commission is not in a position to ascertain whether the Member State has genuinely implemented the directive completely. The failure of a Member State to fulfil that obligation, whether by providing no information at all or by providing insufficiently clear and precise information, may of itself justify recourse to the procedure under Article 226 EC in order to establish the failure to fulfil the obligation (Case 96/81 Commission v Netherlands, cited above, paragraph 8).
28 In the present case, it is common ground that the Italian Government not only did not reply to the Commission's letter of formal notice but additionally did not state in its response to the reasoned opinion that the Directive was to be regarded as already transposed by the domestic law in force. Quite to the contrary, since it informed the Commission, both in its response to the reasoned opinion and in its subsequent letter of 10 July 2003, of the fact that the provisions needed to transpose the Directive were about to be adopted, the Italian Government implicitly, but certainly, gave the Commission to understand that the domestic law in force was not capable, without the adoption of specific measures, of transposing the Directive correctly and completely.
29 In those circumstances, the Italian Government cannot complain that the Commission, in its application, simply stated that the Directive had not been transposed at all within the period laid down and did not seek to show in what way the provisions of Italian domestic law in force did not comply with the Directive. As the Advocate General has stated in point 43 of his Opinion, the alleged lack of precision in the application results from the Italian Government's own conduct during the pre-litigation procedure (see, to this effect, Case C-408/97 Commission v Netherlands, cited above, paragraph 17).
30 That finding is not called into question by the fact that Article 1(1) of the Directive provides that the Member States are, 'if necessary', to adjust their national patent law to take account of the Directive's provisions. While this article allows the Member States to secure the substantive transposition of the Directive by means of their domestic legal rules in force, it does not in any event absolve them from the formal obligation to inform the Commission of the existence of those rules so that it can be in a position to assess whether the rules comply with the Directive.
31 Consequently, the Italian Government's present argument must be rejected. To the extent that, as to the remainder, the Italian Republic's line of argument seeks to dispute the allegation that it has failed to fulfil its obligations, that failure is to be examined when considering the substance.
32 So far as concerns, second, the admissibility of the arguments put forward in the reply in order to demonstrate that the domestic law in force did not comply with certain provisions of the Directive, it is to be remembered that it was only in its defence that the Italian Government pleaded that the domestic law in force complied with the Directive.
33 In these circumstances, the Commission cannot be reproached for having responded to those arguments for the first time in its reply; the Commission is entitled, as the Court has held, to clarify the form of order sought in order to take into account information furnished by a Member State in its defence (Case C-243/89 Commission v Denmark [1993] ECR I-3353, paragraph 20). Also, Article 42 (2) of the Rules of Procedure expressly provides that a party is entitled to introduce a new plea in law in the course of proceedings in order to take account of matters of law or fact which come to light in the course of the procedure.
34 Consequently, the Italian Government cannot complain that the Commission put forward in its reply arguments which did not appear in its application.
35 It is, however, to be remembered that, in accordance with settled case-law, the subject-matter of an action under Article 226 EC for failure to fulfil obligations is also delimited by the pre-litigation procedure provided for by that provision, so that the application must be based on the same grounds and pleas as the reasoned opinion (see, inter alia, Case C-96/95 Commission v Germany [1997] ECR I-1653, paragraph 23, Case C-439/99 Commission v Italy [2002] ECR I-305, paragraph 11, and Case C-287/00 Commission v Germany [2002] ECR I-5811, paragraph 18).
36 According to the case-law, the purpose of the pre-litigation procedure is to give the State concerned the opportunity, on the one hand, to comply with its obligations under Community law and, on the other, to avail itself of its right to defend itself against the complaints

formulated by the Commission (see Case C-392/96 Commission v Ireland [1999] ECR I-5901, paragraph 51, Commission v Italy, cited above, paragraph 10, and Case C-117/02 Commission v Portugal [2004] ECR I-5517, paragraph 53).

37 The proper conduct of that procedure constitutes an essential guarantee required by the Treaty not only in order to protect the rights of the Member State concerned, but also so as to ensure that any contentious procedure will have a clearly defined dispute as its subject-matter (see Case C-1/00 Commission v France [2001] ECR I-9989, paragraph 53, and Case C-287/00 Commission v Germany, cited above, paragraph 17).

38 In the present case, it is clear that, as the Italian Government submits, in complaining in the course of the pre-litigation procedure that the Italian Republic had not adopted the provisions necessary to comply with the Directive, the Commission was essentially alleging that the Italian Republic had not transposed the Directive at all. On the other hand, in the arguments put forward in its reply regarding the domestic law in force, the Commission submits that the Italian Republic has not transposed certain provisions of the Directive, thereby requiring the domestic law in force to be examined in detail in order to ascertain which of those provisions have not in fact been transposed correctly or completely.

39 However, the requirement that the subject-matter of an action brought under Article 226 EC be circumscribed by the pre-litigation procedure provided for by that provision cannot be stretched so far as to mean that in every case the statement of complaints set out in the letter of formal notice, the operative part of the reasoned opinion and the form of order sought by the action must be exactly the same, provided that the subject-matter of the proceedings has not been extended or altered (see, to this effect, Case C-279/94 Commission v Italy [1997] ECR I-4743, paragraph 25, and Case C-139/00 Commission v Spain [2002] ECR I-6407, paragraph 19).

40 That is the case where, as here, the Commission, after alleging that a Member State has failed to transpose a directive at all, specifies in its reply that the transposition pleaded for the first time by the Member State concerned in its defence is in any event incorrect or incomplete so far as certain provisions of the directive are concerned. Such a complaint is necessarily included in the complaint alleging a complete failure to transpose and is subsidiary to that complaint (see, to this effect, Commission v Portugal, cited above, paragraph 55).

41 It should be noted that in this instance the pre-litigation procedure attained its objective of protecting the rights of the Member State in question. The Italian Republic had the opportunity to comply with its obligations under the Directive since, as its response to the reasoned opinion and its subsequent letter of 10 July 2003 attest, it informed the Commission of the point reached in the procedure for adoption of the legislation envisaged for that purpose. In addition, the Italian Republic had the opportunity, in the course of this procedural phase, to show that its domestic law in force complied with the requirements laid down by the Directive, even if it considered it unnecessary to avail itself of that opportunity in this instance (see, in this regard, Case 274/83 Commission v Italy [1985] ECR 1077, paragraph 20).

42 Consequently, the Italian Government cannot complain that the Commission has extended or altered the subject-matter of the action as defined by the pre-litigation procedure.

43 In light of those considerations, the Italian Government's objections seeking to contest the admissibility of the present action must be rejected in their entirety.

Substance

44 In the form of order sought as set out in its application, the Commission complains that the Italian Republic has failed to adopt the provisions necessary to comply with the Directive. In its reply it submits 'for completeness' in response to the arguments put forward by the Italian Republic in this respect that the domestic law in force does not, in any event, comply with the Directive, in particular in as much as it does not adequately transpose Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive.

45 The Italian Government concedes that the Law transposing the Directive was not adopted within the period laid down by the Directive, since the legislative procedure was in progress. However, it submits that as the Commission did not adduce proof in its application that the domestic law in force did not comply with the Directive, the action must be dismissed. In any event, the Italian Government considers that domestic patent law complies with the Directive.

46 It is to be noted first of all that, as is common ground, the Italian Government, contrary to its obligation under Article 10 EC and Article 15 of the Directive, did not inform the Commission, whether during the period for transposition or during the pre-litigation procedure, of the domestic legal measures by means of which it considered that it had transposed the Directive. For the reasons set out in paragraph 30 of this judgment, it is irrelevant in this regard that the transposition pleaded did not have to be carried out because the domestic law in force complied with the Directive.

47 However, since the present action concerns not a failure to fulfil the obligation to provide information but a failure to fulfil the obligation to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive, the mere fact that the Italian Republic did not inform the Commission that, in its view, the Directive was already transposed by the domestic law in force cannot, contrary to what the Commission appears to suggest, be sufficient to prove the alleged failure to fulfil an obligation.

48 In so far as the domestic legal provisions pleaded by the Italian Government were in force when the period set in the reasoned opinion expired, the Court must take them into account when determining whether that obligation has not been fulfilled (see, to this effect, Case C-152/98 Commission v Netherlands [2001] ECR I-3463, paragraph 21).

49 Accordingly, given the subject-matter of the action, in examining its merits the provisions of the Directive should be compared with the national laws, regulations and administrative measures by which the Italian Republic considers that it has implemented the Directive, in order to establish whether they transpose it adequately.
50 It should be remembered that, according to settled case-law, each of the Member States to which a directive is addressed is obliged to adopt, within the framework of its national legal system, all the measures necessary to ensure that the directive is fully effective, in accordance with the objective that it pursues (see, inter alia, Case C-478/99 Commission v Sweden [2002] ECR I-4147, paragraph 15, and Case C-233/00 Commission v France [2003] ECR I-6625, paragraph 75).
51 While it is therefore essential that the legal situation resulting from national implementing measures is sufficiently precise and clear to enable the individuals concerned to know the extent of their rights and obligations, it is none the less the case that, according to the very words of the third paragraph of Article 249 EC, Member States may choose the form and methods for implementing directives which best ensure the result to be achieved by the directives, and that provision shows that the transposition of a directive into national law does not necessarily require legislative action in each Member State. The Court has thus repeatedly held that it is not always necessary formally to enact the requirements of a directive in a specific express legal provision, since the general legal context may be sufficient for implementation of a directive, depending on its content. In particular, the existence of general principles of constitutional or administrative law may render superfluous transposition by specific legislative or regulatory measures provided, however, that those principles actually ensure the full application of the directive by the national authorities and that, where the relevant provision of the directive seeks to create rights for individuals, the legal situation arising from those principles is sufficiently precise and clear and that the persons concerned are put in a position to know the full extent of their rights and, where appropriate, to be able to rely on them before the national courts (see, inter alia, Case 29/84 Commission v Germany [1985] ECR 1661, paragraphs 22 and 23, and Case C-233/00 Commission v France, cited above, paragraph 76).
52 Consequently, it is important in each individual case to determine the nature of the provision, laid down in a directive, to which the action for failure to fulfil obligations relates, in order to gauge the extent of the obligation to transpose imposed on the Member States (Case C-233/00 Commission v France, paragraph 77).
53 It is in the light of those considerations that the various complaints raised by the Commission to demonstrate incomplete or incorrect transposition of the Directive should be examined. The complaint alleging breach of Article 3(1) of the Directive
54 The Commission pleads that Italian legislation, in particular Article 12 of Royal Decree No 1127/39, contains no provision relating to the possibility of obtaining a patent for an invention concerning a product consisting of or containing biological material.
55 According to the Italian Government, the term 'industrial invention' adopted by Article 12 of Royal Decree No 1127/39 and as interpreted by national case-law is, however, broad enough to include biological material.
56 As to those submissions, by virtue of Article 3(1) of the Directive inventions which are new, involve an inventive step and are susceptible of industrial application are to 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.
57 It follows from the very wording of this provision that it provides for a specific right allowing inventions making use of biological material to be patented, by requiring the Member States, as is apparent from the third and eighth recitals in the preamble to the Directive, to adapt or add to national patent law in order to ensure effective and harmonised protection of biotechnological inventions that is such as to maintain and encourage investment in that field.
58 The Court has already held that, by requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive aims to prevent damage to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection (Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-7079, paragraph 18). In so doing, the Directive seeks, as is apparent from the fourth, fifth and sixth recitals in its preamble, to clarify the legal protection of biotechnological inventions in a context marked by differences between national laws and practices that could well become greater, in particular as a result of national case-law interpreting those laws.
59 In the present case, it is not in dispute that Italian patent law does not expressly provide that inventions making use of biological material are patentable, since Article 12 of Royal Decree No 1127/39, which is relied on by the Italian Government in this connection, does no more than set out generally the conditions for the patentability of any invention.
60 Furthermore, while the Italian Government submits that the national courts interpret broadly the term 'invention' adopted by domestic patent law, it has not cited any judicial decision affirming the patentability of inventions making use of biological material.
61 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to whether it is possible to obtain protection for biotechnological inventions under Italian patent law.
62 Consequently, the Commission's complaint alleging breach of Article 3(1) of the Directive is well founded.
The complaint alleging breach of Article 5(2) of the Directive
63 The Commission submits that Italian legislation does not provide for the possibility of patenting an

element isolated from the human body or otherwise produced by means of a technical process.
64 The Italian Government contends that Article 13 of Royal Decree No 1127/39 complies with Article 5(2) of the Directive. In addition, the only rule-making element of this provision is to be found in the final part of the sentence, according to which a genetic sequence 'may constitute a patentable invention, even if the structure of that element is identical to that of a natural element'. Given the broad definition adopted by national case-law of the term 'invention', the patentability of artificial reproduction of an element present in nature has never been precluded.
65 As to those submissions, under Article 5(2) of the Directive 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.
66 As the Court has held in this connection, the elements of the human body are not patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent (Netherlands v Parliament and Council, cited above, paragraph 72).
67 Thus, as is stated in the 20th and 21st recitals in the preamble to the Directive, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated (Netherlands v Parliament and Council, paragraph 73).
68 That distinction applies to work on the sequence or partial sequence of human genes. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by Article 5(3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the discovery of a DNA sequence, which would not be patentable as such (Netherlands v Parliament and Council, paragraph 74).
69 Thus, the protection envisaged by the Directive covers only the result of inventive scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application (Netherlands v Parliament and Council, paragraph 75).
70 It follows that Article 5(2) of the Directive thus seeks to grant specific rights as regards the patentability of elements of the human body. Even though it provides merely for the possibility that a patent be granted, it obliges the Member States, as is apparent from the 17th to 20th recitals in the preamble to the Directive, to provide that their national law does not preclude the patentability of elements isolated from the human body, in order to encourage research aimed at obtaining and isolating such elements valuable to medicinal production.
71 In the present case, it is clear that Italian patent law makes no provision for the possibility of elements isolated from the human body constituting a patentable invention. In particular, contrary to the Italian Government's submissions, Article 13 of Royal Decree No 1127/39 contains no provision to this effect.
72 Furthermore, while the Italian Government submits that the national courts interpret broadly the term 'invention' adopted by domestic patent law, it has not cited any judicial decision acknowledging that it is possible to patent elements isolated from the human body.
73 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to whether it is possible to obtain protection for such elements under Italian patent law.
74 Consequently, the Commission's complaint alleging breach of Article 5(2) of the Directive is well founded.
The complaint alleging breach of Article 6(2) of the Directive
75 The Commission observes that Italian legislation, in particular Article 13 of Royal Decree No 1127/39, does not lay down that certain specific processes, such as the cloning of human beings and uses of human embryos for industrial and commercial purposes, are not patentable. Law No 40 of 19 February 2004 on medically assisted reproduction (GURI, No 45, of 24 February 2004; 'Law No 40/2004') which prohibits physical activities relating to embryos does not relate to the patentability of inventions.
76 The Italian Government contends that Article 13 of Law No 40/2004, read in conjunction with Article 13 of Royal Decree No 1127/39, implements adequately the principles laid down in Article 6 (2) of the Directive, since Law No 40/2004 classifies human cloning and modification of the genetic identity of human beings as practices contrary to public policy and morality and therefore prevents them from being patentable. It further submits that Article 5 of the Civil Code prohibits acts of disposition of the human body, so that any processes intended to modify the genetic identity of a human being cannot have patent protection under Italian law.
77 It is to be remembered that, by virtue of Article 6(2) of the Directive, the following, in particular, are to be considered unpatentable: processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; and 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.
78 Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public (public policy) and morality, Article 6(2) allows the Member States no

discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, Netherlands v Parliament and Council, paragraphs 37 to 39). It is apparent from the 40th recital in the preamble to the Directive that processes for cloning human beings must be excluded 'unequivocally' from patentability, since there is a consensus on this question within the Community.

79 It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard.

80 It is clear that neither Article 13 of Royal Decree No 1127/39 nor Article 5 of the Civil Code provides expressly that the processes and uses set out in Article 6(2) of the Directive are not patentable, since those provisions merely preclude in general terms, respectively, the patentability of inventions whose exploitation would be contrary to public policy and morality and acts of disposition of the human body.

81 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to the patentability of the processes and uses concerned.

82 This uncertainty constitutes a breach of the Directive all the more because Article 6(1) thereof itself states that the commercial exploitation of an invention is not to be deemed contrary to order public or morality merely because it is prohibited by law or regulation. As the Advocate General has correctly observed in point 55 of his Opinion, this statement is to be interpreted as requiring express transposition of the principle that commercial processes involving the use of human embryos are not patentable.

83 As to the provisions of Law No 40/2004, it is common ground that this Law was adopted after the time-limit set in the reasoned opinion. It is settled case-law that in the context of proceedings under Article 226 EC the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion, and the Court cannot take account of any subsequent changes (see, inter alia, Case C-378/98 Commission v Belgium [2001] ECR I-5107, paragraph 25, and Case C- 352/02 Commission v Greece [2003] ECR I-5651, paragraph 8).

84 Therefore, the Commission's complaint alleging breach of Article 6(2) of the Directive is well founded.

The complaint alleging breach of Articles 8 to 11 of the Directive

85 The Commission pleads that Italian legislation does not contain any provision concerning the scope of the protection conferred by a patent relating to a biotechnological invention, in breach of Articles 8 to 11 of the Directive.

86 The Italian Government contends, however, that Article 1bis of Royal Decree No 1127/39 provides for protection conferred by a patent that is as wide as the protection prescribed by those provisions of the Directive, inasmuch as the latter merely extend the protection given by a patent relating to a biotechnological invention to material resulting directly from the application of the patented process.

87 As to those submissions, Articles 8 to 11 of the Directive clearly seek to grant specific rights since they define the scope of protection conferred by patents relating to a biological invention.

88 In the present case, since Italian law does not expressly provide that biological inventions are patentable, it is undisputed that it likewise does not contain provisions specifying the scope of the protection conferred by a patent relating to such an invention.

89 Article 1bis of Royal Decree No 1127/39 simply defines generally the rights conferred by any patent relating to any product or process. On the other hand that provision, contrary to the requirements of Articles 8 and 9 of the Directive, does not refer to the scope of the rights specifically conferred by the various types of patents envisaged by those provisions, namely patents on biological material, patents on a process that enables a biological material to be produced and patents on a product containing or consisting of genetic information.

90 Thus, although it is correct, as the Italian Government submits, that Article 1bis(1)(b) of Royal Decree No 1127/39 provides that a patent on a process confers on its holder the right to prohibit third parties from using the product directly obtained from that process, the fact remains that this provision does not require, as Article 8(2) of the Directive does, that 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 is to extend to biological material directly obtained through that process and to any other biological material derived through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

91 Nor, contrary to Articles 8(1) and 9 of the Directive, does Italian patent law provide that the protection conferred, first, by a patent on biological material and, second, by a patent on a product containing or consisting of genetic information extends, respectively, to any biological material derived from that biological material through propagation or multiplication, and to all material in which the product is incorporated and in which the genetic information performs its function.

92 Furthermore, Article 1bis of Royal Decree No 1127/39 does not contain any of the restrictions and derogations provided for in Articles 10 and 11 of the Directive.

93 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to the precise extent of the protection conferred by a patent relating to a biological invention.

94 Therefore, the Commission's complaint alleging breach of Articles 8 to 11 of the Directive is well founded.

The complaint alleging breach of Article 12 of the Directive

95 The Commission submits that Article 54 of Royal Decree No 1127/39, which provides for the grant of compulsory licences, does not take account of the case where there is a relationship of interdependence between a patent on a biotechnological invention and a regime governing plant variety rights.

96 The Italian Government points out that, in the situation referred to in Article 12 of the Directive, the Italian authorities do not in practice have any discretion notwithstanding the use of the words 'may be granted' in Article 54 of Royal Decree No 1127/39 and that they are therefore required to grant the compulsory licence applied for.

97 Under Article 12 of the Directive, a non-exclusive compulsory licence may be applied for, first, in respect of a prior patent, by the holder of a plant variety right and, second, in respect of a prior plant variety right, by the holder of a patent on a biotechnological invention, where the exploitation of their plant variety right and patent respectively would infringe those prior rights.

98 It is manifest that such a provision, which provides for the grant of a compulsory licence to exploit an invention protected by a patent or by a plant variety right, seeks to confer specific rights in this regard.

99 While Article 54(2) of Royal Decree No 1127/39 provides for the grant of a compulsory licence where an invention protected by a patent cannot be used without infringing the rights arising from another, prior, patent, it does not provide, as Article 12(1) and (2) of the Directive does, for the grant of such a licence in the case of interdependence between a patent on a biotechnological invention and a plant variety right. Furthermore, Article 54(2) of Royal Decree No 1127/39 does not oblige the applicant for the compulsory licence either to pay an appropriate royalty, as Article 12(1) and (2) of the Directive requires, or to have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence, as Article 12(3) of the Directive prescribes.

100 Accordingly, the Commission's complaint alleging breach of Article 12 of the Directive is well founded.

The complaint alleging a failure to transpose the other provisions of the Directive

101 Despite the specific complaints which it raised in its reply, concerning breach by the Italian Republic of certain provisions of the Directive, the Commission has not modified the initial subject of its application, which essentially seeks a declaration that the Italian Republic has failed to transpose the Directive at all.

102 According to the case-law, in proceedings for failure to fulfil obligations under Article 226 EC it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled and in so doing it may not rely on any presumption (see, inter alia, Case 96/81 Commission v Netherlands, cited above, paragraph 6, Case C-408/97 Commission v Netherlands, cited above, paragraph 15, and Commission v Portugal, cited above, paragraph 80).

103 Therefore, since the Italian Government contended in its defence that the Italian domestic law in force complied with the Directive, the Commission had the task, in order to prove that the Directive had not been transposed at all, of placing before the Court the information needed to enable the latter to establish that such a failure to fulfil obligations had occurred.

104 It is clear, however, that in its reply the Commission provides such information only in relation to Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive, with which the complaints examined above were concerned, and not in relation to all the remaining provisions of the Directive.

105 Contrary to what the Commission appears to suggest, the mere fact that certain provisions of the Directive, put forward by way of example, cannot be regarded as having been transposed correctly by the domestic law in force does not establish in the slightest that the remaining provisions of the Directive cannot be regarded as being correctly transposed by the domestic law in force.

106 Accordingly, since the Commission has adduced no probative evidence in this regard, the action must be dismissed in so far as it seeks a declaration that the Italian Republic has failed to transpose the Directive at all.

107 In light of all the foregoing considerations, it is to be held that, by having failed to adopt the laws, regulations and administrative provisions necessary to comply with Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive, the Italian Republic has failed to fulfil its obligations under Article 15 of the Directive.

108 The remainder of the application must be dismissed.

Costs

109 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

110 Under the first subparagraph of Article 69(3) of the Rules of Procedure, the Court may order that the costs be shared or that the parties bear their own costs in particular where each party succeeds on some and fails on other heads. However, by virtue of the second subparagraph of Article 69(3), the Court may also order a party, even if successful, to pay costs which the Court considers that party to have unreasonably or vexatiously caused the opposite party to incur,.

111 In the present case, the Commission has been partially unsuccessful in its pleas, in that it sought a declaration that the Italian Republic had failed to transpose the Directive at all.

112 In these circumstances, since the Italian Republic has not applied for the Commission to pay the costs it must be ordered to bear its own costs.

113 As regards the Commission's costs, since the Italian Republic did not provide all the relevant information concerning the domestic legal provisions by means of which it considered that it had fulfilled the various obligations imposed on it by the Directive, it cannot be held against the Commission that it brought before the Court infringement proceedings seeking a

declaration that the Directive had not been transposed at all, rather than a declaration that some of its provisions had not been transposed completely or correctly.
114 Furthermore, by not permitting the Commission to examine in the course of the pre-litigation procedure whether the domestic law pleaded complies with the Directive, the Italian Republic also required the Commission to devote resources thereto in the course of the contentious procedure, thus obstructing, as the Advocate General has rightly pointed out in paragraph 67 of his Opinion, the normal course of the proceedings by an evasive procedural strategy.
115 Consequently, the Italian Republic must be ordered to bear all the costs.
On those grounds, the Court (Third Chamber) hereby:
1. Declares that, by having failed to adopt the laws, regulations and administrative provisions necessary to comply with Articles 3(1), 5(2), 6(2) and 8 to 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the Italian Republic has failed to fulfil its obligations under Article 15 of that directive;
2. Dismisses the action as to the remainder;
3. Orders the Italian Republic to bear all the costs

OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER
delivered on 10 March 2005 (1)
Case C-456/03
Commission of the European Communities
v
Italian Republic
(Failure of a Member State to fulfil its obligations – Legal protection of biotechnological inventions)
1. The Commission seeks a declaration that Italy has failed to fulfil its obligations under the harmonising legislation on biotechnological patents.
2. What is unusual about these proceedings is that it was only in its defence that the defendant Member State contested the Commission's claims. The attitude of the defendant during the administrative phase could have led the Commission to conclude that the defendant tacitly acknowledged the alleged breach, since the defendant maintained that the relevant implementing legislation was shortly to be enacted.
3. Furthermore, the defendant's stance has limited the exchange of arguments between the parties, to the detriment of the proper conduct of these proceedings for infringement of the Treaty. Directive 98/44
4. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 (hereinafter 'the Directive') (2) is aimed at harmonising the legislation of the Member States on the legal protection of biotechnological inventions.

The Directive was adopted pursuant to Article 189b of the EC Treaty (now, after amendment, Article 251 EC).
5. It is important to note that, according to the preamble, the Directive seeks to clarify the legal protection of biotechnological inventions (fourth recital), following establishment of the fact that differences exist in the laws and practices of the different Member States which could create barriers to trade and hence impede the proper functioning of the internal market (fifth recital). The preamble goes on to state that uncoordinated development of those national systems is detrimental to the industrial development of such inventions (seventh recital), notwithstanding which, in the opinion of the European Parliament and the Council, it is not necessary to create a separate body of law and it will suffice for the rules of national patent law to remain the essential basis, albeit adapted or added to, for the legal protection of biotechnological inventions (eighth recital).
6. The ninth recital in the preamble states that since, in certain cases, such as the exclusion from patentability (3) 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 conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions, that uncertainty must be clarified by means of harmonisation.
7. In accordance with the 13th recital in the preamble to the Directive, 'the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such, such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely'.
8. The preamble also states that it would be advantageous to encourage, by means of the patent system, progress in the treatment of diseases thanks to the existence of medicinal products derived from elements isolated from the human body or from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body (17th recital). However, since the patent system alone is insufficient to encourage research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem (18th recital). Finally, the Community legislature makes it clear that an invention susceptible of industrial application which is based on an element isolated from the human body or otherwise produced by means of a technical process 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 (20th recital).
9. Article 1(1) of the Directive provides: '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 this Directive.'
10. Under Article 3(1) of the 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'.
11. In accordance with Article 5(2) of the Directive, '[a]n 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'.
12. 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.'
13. Chapter II of the Directive concerns the scope of the protection conferred by a biotechnological patent. It contains the following provisions:
Article 8
'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.'
Article 9
'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.'
Article 10
'The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.'
Article 11
'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.'
14. With regard to compulsory cross-licensing, Article 12 of the Directive provides:
'1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.
2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.
3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.
4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.'
15. Pursuant to Article 15, Member States were required to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive not later than 30 July 2000, and forthwith to inform the Commission thereof.

The prior administrative procedure

16. Italy did not inform the Commission that it had enacted any of the measures required in theDirective. Since the Commission had no reason to believe that the defendant Member State had transposed the provisions of the Directive into national law, on 20 November 2000 it sent that Member State a letter requiring it to do so, in accordance with the procedure laid down in Article 226 EC.
17. The Commission did not receive a reply to that letter and, therefore, on 19 December 2002, it sent the Italian authorities a reasoned opinion in which it stated that, by failing to adopt the laws, regulations and administrative provisions required to transpose the Directive into national law, the Italian Republic had failed to fulfil its obligations under the Treaty, and granted the Italian Republic a period of two months in which to effect the transposition.
18. On 6 February 2003, Italy's Permanent Representation to the European Union sent a letter to the Commission in which it stated that no measures implementing the Directive had yet been enacted. In a subsequent letter, dated 10 July 2003, the Permanent Representation stated that the procedure for drawing up the said measures was at an advanced stage.

Procedure before the Court of Justice

19. Since it had received no further information, the Commission brought this action, which was lodged at the Court Registry on 27 October 2003.
20. The application, defence, reply and rejoinder were lodged, following which neither party requested a hearing. I find surprising that waiver of a procedural stage during which the Commission would at least have had the opportunity to put forward its view regarding the total failure of the defendant to cooperate in good faith throughout these proceedings for failure to fulfil an obligation.

Arguments of the parties

21. In the application, the Commission merely complained that the defendant had failed to transpose the provisions of the Directive into national law, and did not elaborate further. It was in the reply, therefore, that the matters at issue in these proceedings were first really debated. That delay in putting forward the claims in these proceedings can be attributed to the attitude of the Italian authorities during the pre-litigation phase.
22. In the defence, the defendant Member State argues that, although the enabling legislation designed to transpose the Directive into national law is still at the drafting stage, the measures currently in force already comply with the principles arising from the Community legislation, and the defendant places on the Commission the burden of proving the alleged breach.
23. The defendant also pleads Article 1 of the Directive, which requires transposition only in the event that it is necessary, and, by way of information, the defendant refers to Royal Decree No 1127 of 29 June 1939, in particular to Articles 12 and 13 thereof. Under Article 12 of the Royal Decree, inventions which involve an inventive step and are susceptible of industrial application are patentable. The provision does not exclude from patentability the items defined therein, with the exception of discoveries, theories, plans, principles, processes and programmes. However, processes for the surgical or therapeutic treatment of humans or animals and diagnostic procedures used on humans or animals are not regarded as inventions for those purposes. Furthermore, when the Corte di cassazione (Court of Cassation) interpreted Article 12 it made the patentability of a chemical invention conditional on the requirement that it must be original, and as such must give rise to a form of intrinsic 'inventive leap' capable of bringing about an evolution in the state of the technology concerned such that it differs from what was available previously; that criterion is akin to the discovery or to the identification of a new use for previously acquired knowledge, since, from a scientific standpoint, the latter are no less important than the 'straightforward' creation of a product. (4)
24. The Italian Government infers from the aforementioned legislation and case-law that the concept of a patentable invention is wide enough in scope to encompass the protection of biotechnological inventions, as defined in Articles 2 and 3 of the Directive.
25. As regards Article 13 of Royal Decree No 1127, although it excludes from patentability inventions whose exploitation would be contrary to public policy or morality, this does not concern a mere legal or administrative prohibition.
Article 13 provides that animal breeds and essentially biological processes for obtaining them are unpatentable. The provision does not apply to microbiological processes or to the product obtained using such processes.
26. The Italian Government claims that the aforementioned provisions are compatible with the requirements of the Directive.
27. With regard to the prohibition of the creation and use of human embryos, the Italian legislation was subsequently supplemented by Articles 13 and 14 of the Law on Medically Assisted Reproduction, which was approved by the Chamber of Deputies on 10 February 2004.
28. Lastly, as regards Article 1(2) of the Directive (continued compliance with the TRIPs Agreement and the

Convention on Biological Diversity), the Italian Government contends that those international agreements were transposed into national law some time ago. More recently, pursuant to Law No 27 of 15 January 2004, the Cartagena Protocol on Biosafety, relating to the Convention on Biological Diversity, also entered into force in Italy. Article 11 et seq. of that protocol govern measures for the prevention of risks linked to the use of living modified organisms, which are patentable under the rules laid down in the Directive.

29. Therefore, the Italian Government argues that it has fulfilled the objectives laid down in the Directive, from both a substantive and a procedural point of view, and on those grounds it claims that the application should be dismissed.

30. In the reply, the Commission puts forward claims of a procedural nature and claims relating to substantive law.

31. In the former, the Commission draws attention to certain aspects of the conduct of the defendant Member State (failure to notify under Article 15(2) of the Directive; tacit admission of the breach during the administrative phase; drafting of legislation aimed at transposing the Directive into national law) in support of its contention that the measures required by the situation were not taken.

32. With regard to substantive law, the Commission 'for completeness' refers to five specific breaches of the Directive where no implementing provisions have been adopted in Italian law:

1. concerning the possibility of obtaining a patent for an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Article 3(1) of the Directive);

2. concerning the possibility of patenting an element isolated from the human body (Article 5(2)), having regard to the fundamental aim of the Directive which is to establish a uniform body of Community law in that sphere (17th to 20th recitals in the preamble to the Directive);

3. concerning the prohibition of patentability in relation to certain specified procedures, such as the cloning of human beings and the use of human embryos for industrial or commercial purposes (Article 6(2));

4. concerning the protection conferred by a patent relating to a biotechnological invention (Articles 8 to 11 of the Directive), which, as the 13th recital in the preamble thereto makes clear, is an essential element of the Directive;

5. specifically concerning the relationship of dependence which can arise between a patent for a biotechnological invention and the system of protection for plant varieties (Article 12).

33. I will analyse the claims put forward in the rejoinder when dealing with the substance of the action and it is therefore unnecessary to go into the details at this juncture.

34. As a preliminary point, it should be recalled that the Court held in Commission v Italy(5) that the transposition of a directive into national law does not necessarily require that its provisions be incorporated formally and verbatim in express specific legislation; a general legal context may, depending on the content of the directive, be adequate for the purpose provided that it does indeed guarantee the full application of the directive in a sufficiently clear and precise manner so that, where the directive is intended to create rights for individuals, the persons concerned may ascertain the full extent of their rights and, where appropriate, rely on them before the national courts. However, in order to secure full implementation of directives in law and not only in fact, Member States must establish a specific legal framework in the area in question. (6)

35. The Commission seeks a declaration against the Italian Republic on account of the latter's conduct during the administrative phase, and, in the alternative, on account of the failure of Italian national legislation to comply with the Community requirements.

36. I should like to begin by pointing out that these proceedings have not been conducted in the normal way or in accordance with the established procedures. Article 226 EC provides for a complex form of action which is designed to ensure that a Member State complies with Community law, and which, as a last resort, can lead to a declaration by the Court of Justice that the Member State concerned has failed to fulfil its obligations. The pre-litigation administrative phase, which concludes with the reasoned opinion of the Commission setting out the breach and fixing a period in which to remedy it, is followed, where applicable, by the judicial phase. However, it is settled case-law that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing at the end of the period laid down in the reasoned opinion for remedying the breach. (7) It is at that point that the subjectmatter of the action is determined, meaning that when the Court rules on the substance it is not required to take into account subsequent events.

37. In the case before the Court, by the end of the period laid down in the reasoned opinion, the Italian Government had already indicated acquiescence by its silence, and had also made a vague reference to draft legislation in progress.

38. The Commission complains about those matters and, while failing to state as much clearly (in the reply the Commission implies that it is dealing with the substantive legal aspects of the action only for the sake of completeness), appears to be of the opinion that such conduct tips the balance in its favour.

39. I do not share that opinion. There is no question that where the conduct of a Member State in proceedings impedes the Commission in its role, entrusted to it under the Treaties, as the guardian of Community law, that Member State deserves to be strongly reprimanded. However, such conduct can lead only to a political or moral reprimand and can never of itself lead to a declaration that the Member State concerned has failed to fulfil its obligations, even where the conduct in question can be classed as a breach of the duty to cooperate in good faith which is incumbent on the Member

States; where applicable, it would be possible for such a breach to be punished by the Court in separate proceedings brought for that purpose.
40. The Commission implies that the attitude of the Italian Government in the pre-litigation phase is tantamount to acquiescence, but, as I pointed out on a previous occasion, (8) it is not for the parties to decide how an action under Article 226 EC is to be disposed of, and the acquiescence or lax attitude of a defendant during such proceedings does not lead automatically to the action against that defendant being upheld.
41. For its part, the defendant claims that the action should be dismissed because the application does not cite any specific complaints.
42. In accordance with Article 21 of the EC Statute of the Court of Justice and Article 38(1)(c) of the Rules of Procedure, the application must contain, inter alia, a brief statement of the pleas in law on which the application is based. In any application made under Article 226 EC, the Commission must indicate the specific complaints on which the Court is called upon to rule and, at the very least in summary form, the legal and factual particulars on which those complaints are based. (9)
43. The Italian Government cannot plead a situation which it helped to create. The lack of precision in the application can be attributed to the conduct of the defendant in the proceedings, from which it follows that that complaint cannot succeed.
44. It is therefore necessary to examine the five complaints put forward by the Commission, since there is no presumption that a Member State has failed to fulfil its obligations and the burden of proof falls on the party alleging that failure. (10)
45. First of all, the Commission complains that Italian law infringes Article 3(1) of the Directive, in that it does not permit the patenting of a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
46. In the defence, the Italian Government cites Articles 12 and 13 of Royal Decree No 1127/39 and the wide definition of patentable inventions contained therein, as interpreted in the case-law of the national courts.
47. The reply does not clarify the extent to which that approach is supposedly contrary to the obligation laid down in Article 3(1) of the Directive and to the aims pursued by the Directive in general. The reply also fails to refute the arguments put forward by the defendant and to prove the breach. Accordingly, the first complaint must be dismissed.
48. Second, the Commission complains that Article 5(2) of the Directive, which permits the patenting of an element isolated from the human body, has not been implemented in Italian law.
49. The Italian Government again refers to the wide definition of a patentable invention which applies in Italy. It adds that the only rule-making aspect of Article 5(2) is in its final phrase, which states ‘even if the structure of that element is identical to that of a natural element’. In the opinion of the Italian Government, such circumstances do not give rise to any difficulty because, under the case-law of the Corte di cassazione, artificial processes capable of bringing about technical progress are patentable and such progress occurs every time a natural function is artificially reproduced.
50. It is appropriate to apply to this complaint the same reasoning as was used with regard to the previous complaint; in other words, no evidence has been adduced to indicate that the definition of a patentable invention which is in force in Italy conflicts with the letter or the spirit of the Community provision, and, in particular, that it threatens the coherence of the Community legal order in that sphere. I do, however, have doubts about the explanation relating to the final phrase of Article 5(2). Nevertheless, that new complaint was not put forward by the applicant on whom it is incumbent to prove the failure to fulfil obligations, nor are there any grounds for the Court to examine the complaint of its own motion.
51. The second complaint must therefore be dismissed in its entirety.
52. The basis for the third complaint is that the requirement that certain processes, such as the cloning of human beings and the use of human embryos for industrial or commercial purposes, are to be regarded as unpatentable has not been transposed into Italian law, as prescribed in Article 6 (2) of the Directive. The Commission is of the opinion that Article 13 of Royal Decree No 1127/39 sets out only the general rule, which prohibits the patenting of inventions where their exploitation would be contrary to public policy or morality, and that, as such, it is an accurate reflection of Article 6(1) of the Directive.
53. The Italian Government pleads Article 13 of Law No 40 of 19 February 2004 on Medically Assisted Reproduction, which prohibits experimentation involving human embryos and provides that the production of human embryos and their selection for eugenic purposes, cloning, and fertilisation by gametes from other species are punishable by a prison sentence, a fine and suspension from professional practice. The Italian Government further claims that legislation of such a nature unequivocally classifies the practices of cloning and of altering a person’s genetic identity as contrary to public policy, thereby categorically precluding the patentability of such practices.
54. As a preliminary point, it is important to note that the national provision referred to was enacted after the expiry of the period laid down in the reasoned opinion, and also after the Commission had brought this action for failure to fulfil obligations on 27 October 2003. Accordingly, the provision cannot be taken into account for the purpose of analysing the conduct complained of.
55. Purely for academic purposes, it is appropriate to point out that notwithstanding that, in the light of the wording of Article 13 of Law No 40/2004, the competent authorities would, pursuant to Article 13 of Royal Decree No 1127/39, probably reject a patent application for processes involving cloning or manipulation of

human embryos for commercial or industrial purposes, Article 6(1) of the Directive requires that inventions be considered unpatentable where their exploitation would be contrary to ordre public (public policy) and provides that 'exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation'. That statement may be interpreted as requiring the transposition of the principle that commercial processes involving the use of human embryos are not patentable. In any event, it is clear from a careful reading of the Directive that the principle must be transposed.

56. For the reasons set out in point 54 of this Opinion, it is appropriate to declare, with regard to the third complaint, that there has been a failure to fulfil obligations.

57. The fourth complaint put forward by the Commission is more ambiguous in nature than the previous ones, and focuses on ascertaining whether, under Italian law, patents in respect of biotechnological inventions receive treatment equivalent to that granted in Articles 8 to 11 of the Directive.

58. The Italian Government claims that those provisions merely extend the protection provided by a biotechnological patent to material resulting from application of the patented process. In its view, Article 1bis(1)(b) of Royal Decree No 1127/39 meets those criteria in that it confers on the holder of the patent the exclusive right to apply a particular process, and to use, market, sell or import for such purposes the product directly obtained from the process concerned.

59. I am not convinced by the defence put forward in that regard. Without undertaking an interpretation of Italian law, it is clear from merely reading Articles 8 to 11 of the Directive and Article 1bis of the Royal Decree that the Community provisions govern specific situations which fall outside the scope of the protection accorded to the product of a patent under the Italian legislation.

60. Thus, for example, Article 8 of the Directive governs the protection of a product but, unlike the Italian legislation, it refers not only to patentable processes but also to the biological material itself, provided that such material is capable of propagation or multiplication. Article 9 of the Directive provides specifically for protection to be extended to products containing patented genetic material in which the latter continues to perform its function. That case differs conceptually from the connection between the process and the product, which is the only case governed by the Italian legislation. Articles 10 and 11 contain specific derogations from the general rule providing for the extension of the protection (propagation or multiplication for placing on the market; specific features of agricultural use) which are not reflected at all in Article 1bis of Royal Decree No 1127/39.

61. On those grounds, it is appropriate to uphold this part of the application.

62. Finally, by its fifth complaint the Commission contends that Italian law contains no provision governing the entitlement of a holder of a registered plant variety right to obtain, on reasonable terms, a compulsory licence from the proprietor of a biotechnological invention where the licence is necessary for the exploitation of the plant variety concerned.

63. The Italian Government invokes Article 5 of Royal Decree No 1127/39, which precludes the application or use of a protected invention to exploit another industrial invention without the consent of the holder. Moreover, the Italian Government states that the Royal Decree provides for an extensive system of compulsory licensing. Article 54(2)(b) of Royal Decree No 1127/39 permits such licences where it is not possible to use the patented invention without infringing rights attaching to a prior patent. In such cases, it is appropriate to grant protection to the holder of the subsequent right to the extent necessary for exploitation of the invention, provided that the latter constitutes significant technical progress of considerable economic importance compared with the first invention. The Italian Government also asserts that, although the wording of the legislation implies that, in principle, the administrative authorities have a margin of discretion when it comes to granting such licences, in practice they grant licences only provided that the other conditions are met.

64. Italian law does not provide for all the cases of compulsory cross-licensing governed by Article 12 of the Directive, although it is clear that both are underpinned by the same philosophy. In addition to the apparently discretionary nature of the licence under Royal Decree No 1127/39, an interpretation of the national legislation by reference to the Directive requires that the rules governing patents be extended by analogy to plant varieties and that the concept of an 'appropriate royalty' as consideration for the use of the licence also be introduced. Furthermore, Article 12(3)(a) expressly makes the grant of a licence conditional on the provision by the applicant of proof that he has applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence, a requirement which is absent from the Italian legislation.

65. For the reasons set out, this part of the application must be declared well founded.

Costs

66. The Italian Republic has not applied for costs from the applicant, and accordingly it must bear its own costs, in accordance with Article 69(5) of the Rules of Procedure.

67. As regards the Commission's costs, given the fact that each party has been partially unsuccessful, and, above all, the evasive procedural strategy of the defendant Member State, which has prevented the proceedings from progressing in the usual manner, I propose that those costs be shared equally between the parties, in accordance with Article 69(3) of the Rules of Procedure.

Conclusion

68. In the light of the foregoing considerations, I propose that the Court of Justice should declare that the Italian Republic has failed to fulfil its obligations under Article 6(2) and Articles 8 to 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inven-

tions, that the remainder of the application should be dismissed, and that the defendant Member State should be expressly ordered to pay its own costs and half of the costs incurred by the Commission.

1 – Original language: Spanish.

2 – OJ 1998 L 213, p. 13.

3 – This footnote is not relevant to the English translation.

4 – Cass. 28 June 2001, No 8879.

5 – Case 363/85 [1987] ECR 1733, paragraph 7.

6 – Case C-131/88 Commission v Germany [1991] ECR I-825, paragraph 8.

7 – See, for example, Case C-152/98 Commission v Netherlands [2001] ECR I-3463, paragraph 21; Case C-384/97 Commission v Greece [2000] ECR I-3823, paragraph 35; and Case C-214/96 Commission v Spain [1998] ECR I-7661, paragraph 25.

8 – Joined Opinion in Case C-367/98 Commission v Portugal, Case C-483/99 Commission v France and Case C-503/99 Commission v Belgium [2002] ECR I-4731, point 76.

9 – Case C-347/88 Commission v Greece [1990] ECR I-4747, paragraph 28.

10 – See particularly Case 96/81 Commission v Netherlands [1982] ECR 1791, paragraph 6; Case C-404/00 Commission v Spain [2003] ECR I-6695, paragraph 26; and Case C-434/01 Commission v United Kingdom [2003] ECR I-13239, paragraph 21.