JUDGMENT OF THE COURT (Third Chamber)

16 June 2005 *

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,

* Language of the case: Italian

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,

gives 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 prohibited 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 inasmuch 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 *ordre 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.**

[Signatures]