Court of Justice EU, 6 July 2010, Monsanto v Cefetra

PATENT LAW

Patent protection DNA-sequence limited to circumstances in which it performs the patented function

- **that Article 9 of the Directive must be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it was patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.**

Exhaustive harmonisation Article 9 Biotech-directive

- **that Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.**

National law precluded from granting broader protection

- **that Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.**

Relationship TRIPS and article 9 Biotech-Directive

- **that Articles 27 and 30 of the TRIPS Agreement do not affect the interpretation given of Article 9 of the Directive.**

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Court of Justice EU, 6 July 2010
(V. Skouris, president, A. Tizzano, K. Lenaerts, J.-C. Bonichot, E. Levits, A. Borg Barthet, J. Malenovský, U. Lõhmus)
Judgement of the Court (Grand Chamber)
6 July 2010 (*)
(Industrial and commercial property – Legal protection of biotechnological inventions – Directive 98/44/EC – Article 9 – Patent protecting a product containing or consisting of genetic information – Material incorporating the product – Protection – Conditions)
In Case C-428/08,
REFERENCE for a preliminary ruling under Article 234 EC from the Rechtbank's-Gravenhage (Netherlands), made by decision of 24 September 2008, received at the Court on 29 September 2008, in the proceedings
Monsanto Technology LLC
v
Cefetra BV,
Cefetra Feed Service BV,
Cefetra Futures BV,
Alfred C. Toepfer International GmbH,
Intervener in support of the defendant:
Argentine State,
THE COURT (Grand Chamber),
composed of V. Skouris, President, A. Tizzano, K. Lenaerts, J.-C. Bonichot, E. Levits, Presidents of Chambers, A. Borg Barthet, J. Malenovský, U. Lõhmus and L. Bay Larsen (Rapporteur), Judges, Advocate General: P. Mengozzi,
Registrar: M. Ferreira, Principal Administrator,
having regard to the written procedure and further to the hearing on 15 December 2009, after considering the observations submitted on behalf of:
– Monsanto Technology LLC, by W.A. Hoyng and F.W.E. Eijsvogels, advocaten,
– Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV and Alfred C. Toepfer International GmbH, by J.J. Allen and H.H. Speyart van Woerden, advocaten,
– the Argentine State, by B. Remiche, avocat, and M. Roosen and V. Cassiers, advocaten,
– the Italian Government, by I. Bruni, acting as Agent, and by D. Del Gaizo, avvocato dello Stato,
– the Netherlands Government, by C. Wissels and M. de Grave, acting as Agents,
– the Portuguese Government, by L. Inez Fernandes, acting as Agent,
– the United Kingdom Government, by S. Ossowski, acting as Agent,
– the European Commission, by H. Krämer and W. Wils, acting as Agents,
after hearing the **Opinion of the Advocate General at the sitting on 9 March 2010,** gives the following
Judgment
1 This reference for a preliminary ruling concerns the interpretation of Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13) ('the Directive').
2 The reference was made in two sets of proceedings between Monsanto Technology LLC ('Monsanto') and, first, Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV (collectively 'Cefetra'), supported by the Argentine State, intervener, and, secondly, Vopak

Agencies Rotterdam BV ('Vopak') and Alfred C. Toepfer International GmbH ('Toepfer'), concerning imports into the European Community in 2005 and 2006 of soy meal from Argentina.

Legal context

International law

3 Article 27(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986- 1994) (OJ 1994 L 336, p. 1) ('the TRIPS Agreement'), provides essentially as follows under the heading 'Patentable subject-matter':

– patents are to be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application; patents are to be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

4 Article 30 of the same agreement, entitled 'Exceptions to Rights Conferred' states that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

European Union law

5 Article 1 of the Directive provides that Member States are to protect biotechnological inventions under national patent law and that, if necessary, they are to adjust the latter to take account of the provisions of that directive. It adds that the Directive is to be without prejudice to the obligations of the Member States pursuant, inter alia, to the TRIPs Agreement.

6 Article 2 of the Directive defines 'biological material' as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

7 Article 3 provides that inventions which are new, which involve an inventive step and which are susceptible of industrial application are to be patentable even if they concern, in particular, a product consisting of or containing biological material. It further states that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

8 Recital 22 in the preamble to the Directive points out that the discussion on the patentability of sequences or partial sequences of genes is controversial. It states that the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application, and that the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed.

9 Recital 23 in the preamble to the Directive states that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. 10 Recital 24 in the preamble to the Directive indicates that, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs.

11 Article 5(3) of the Directive, contained in Chapter I, entitled 'Patentability', requires that the industrial application of a sequence or a partial sequence of a gene be disclosed in the patent application.

12 Article 9, contained in Chapter II, entitled 'Scope of protection', provides:

'The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material … in which the product is incorporated and in which the genetic information is contained and performs its function.'

National law

13 Article 53 of the 1995 Netherlands Law on patents (Rijksoctrooiwet 1995) ('the 1995 Law') provides:

'… A patent shall give the patent holder … the exclusive right:

(a) to manufacture the patented product in or for its business, to use it, to bring it into circulation or to sell it on, to hire it out, to deliver it or otherwise trade in it, or to offer it, to import it or to have it in stock for any of those purposes;

(b) to apply the patented process in or for its business, or to use, to bring into circulation or to sell on, to hire out or deliver the product derived directly from the application of that process, or otherwise to trade in that product, or to offer it, to import it or have it in stock for any of those purposes.'

14 Article 53a of that law reads as follows:

'1. In respect of a patent on a biological material possessing specific characteristics as a result of the invention, the exclusive right 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. In respect of a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention, the exclusive right 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.

3. In respect of a patent on a product containing or consisting of genetic information, the exclusive right shall extend to all material in which the product is incorpo-

rated and in which the genetic information is contained and performs its function …'.

The dispute in the main proceedings and the questions referred for a preliminary ruling

15 Monsanto is the holder of European patent EP 0 546 090 granted on 19 June 1996 relating to 'Glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthases' ('the European patent'). The European patent is valid, inter alia, in the Netherlands.

16 Glyphosate is a non-selective herbicide. In a plant, it works by inhibiting the Class I enzyme 5-enolpyruvylshikimate- 3-phosphate synthase (also called 'EPSPS'), which plays an important role in the growth of the plant. The effect of glyphosate is that the plant dies.

17 The European patent describes a class of EPSPS enzymes which are not sensitive to glyphosate. Plants containing such enzymes survive the use of glyphosate, whilst weeds are destroyed. The genes encoding these Class II enzymes have been isolated from three different bacteria. Monsanto has inserted those genes into the DNA of a soy plant it has called RR (Roundup Ready) soybean plant. As a result, the RR soybean plant produces a Class II EPSPS enzyme called CP4-EPSPS, which is glyphosate-resistant. It thus becomes resistant to the herbicide 'Roundup'.

18 The RR soybean is cultivated on a large scale in Argentina, where there is no patent protection for the Monsanto invention.

19 Cefetra and Toepfer trade in soy meal. Three cargoes of soy meal from Argentina arrived in the port of Amsterdam on 16 June 2005, 21 March and 11 May 2006. Vopak made a customs declaration for one of the cargoes.

20 The three consignments were detained by the customs authorities pursuant to Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights (OJ 2003 L 196, p. 7). They were released after Monsanto had taken samples. Monsanto tested the samples to determine whether they originated from RR soybeans.

21 Following the tests, which revealed the presence of CP4-EPSPS in the soy meal and the DNA sequence encoding it, Monsanto applied for injunctions against Cefetra, Vopak and Toepfler before the Rechtbank's-Gravenhage, on the basis of Article 16 of Regulation No 1383/2003, and for a prohibition of infringement of the European patent in all countries in which the patent is valid. The Argentine State intervened in support of the forms of order sought by Cefetra.

22 The Rechtbank's-Gravenhage considers that Monsanto has established the presence, in one of the disputed cargoes, of the DNA sequence protected by its European patent. It is nevertheless unsure as to whether that presence alone is sufficient to constitute infringement of Monsanto's European patent when the soy meal is marketed in the Community.

23 Cefetra, supported by the Argentine State, and Toepfer, argue that Article 53a of the 1995 Law is exhaustive in character. It should be regarded as a lex specialis which derogates from the general protection scheme established by Article 53 of the same law for a patented product. If the DNA present in the soy meal can no longer perform its function in that substance, Monsanto cannot oppose the marketing of the soy meal solely on the ground that the DNA is present in it. There is a connection between the limited patentability referred to in recitals 23 and 24 in the preamble to the Directive and the scope of the protection conferred by a patent.

24 Monsanto argues that the purpose of the Directive is not to limit the protection for biotechnological inventions that exists in Member States. The Directive does not affect the protection conferred by Article 53 of the 1995 Law, which is absolute. A restriction on protection would be incompatible with Article 27 of the TRIPS Agreement.

25 The Rechtbank's-Gravenhage observes that Article 53a(3) of the 1995 Law, like Article 9 of the Directive, places all material in which the DNA is incorporated within the scope of the exclusive right of the proprietor of the patent if the genetic information is found in that material and performs its function therein.

26 It concludes that the DNA cannot perform its function in soy meal, which is dead material.

27 It considers that the wording of Article 53a(3) of the 1995 Law and Article 9 of the Directive does not support the position taken by Monsanto to the effect that it is sufficient that the DNA has performed its function in the soy plant at a given moment or that it could again perform that function after it has been isolated from the soy meal and transferred to living material.

28 The Rechtbank's-Gravenhage adds, however, that a gene, even as part of an organism, does not necessarily have to perform its function on a continuous basis. Thus, there are genes which are activated only in certain stress situations such as heat, dry conditions or disease.

29 Lastly, the fact that, during the cultivation of the soy plants from which the meal was made, profit was had from the invention without any reciprocal compensation is not devoid of significance.

30 If the trade in the soy meal cannot be opposed on the basis of Article 53a(3) of the 1995 Law, which transposes Article 9 of the Directive, it then becomes relevant to ask whether classic, absolute protection such as that provided for by Article 53 of the 1995 Law could be relied on.

31 In that regard, it would appear that the Directive does not detract from the absolute product protection conferred by a provision such as Article 53 of the 1995 Law, but rather strives for minimum protection. However, the indicia supporting such an interpretation are not sufficiently clear.

32 In that context, the Rechtbank's-Gravenhage decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'(1) Must Article 9 of Directive 98/44 … be interpreted as meaning that the protection provided under that pro-

vision can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism?

(2) Proceeding on the basis that the DNA sequence described in claim 6 of patent No EP 0 546 090 is present in the soy meal imported into the Community by Cefetra and [Toepfer], and that the DNA is incorporated in the soy meal for the purposes of Article 9 of [the Directive] and that it does not perform its function therein: does the protection of a patent on biological material as provided for under [the Directive], in particular under Article 9 thereof, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether that DNA performs its function, and must the protection as provided under Article 9 of [the Directive] therefore be deemed to be exhaustive in the situation referred to in that provision, in which the product consists in genetic information or contains such information, and the product is incorporated in material which contains the genetic information?

(3) Does it make any difference, for the purpose of answering the previous question, that patent No EP 0 546 090 was applied for and granted (on 19 June 1996) prior to the adoption of [the Directive] and that such absolute product protection was granted under national patent legislation prior to the adoption of that directive?

(4) Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?'

The questions referred for a preliminary ruling

The first question

33 By its first question, the national court asks, essentially, whether Article 9 of the Directive is to be interpreted as conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it was patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform its function after it has been extracted from the soy meal and inserted into the cell of a living organism.

34 In that regard, it must be noted that Article 9 of the Directive makes the protection for which it provides subject to the condition that the genetic information contained in the patented product or constituting that product 'performs' its function in the 'material … in which' that information is contained.

35 The usual meaning of the present tense used by the Community legislature and of the phrase 'material … in which' implies that the function is being performed at the present time and in the actual material in which the DNA sequence containing the genetic information is found.

36 In the case of genetic information such as that at issue in the main proceedings, the function of the invention is performed when the genetic information protects the biological material in which it is incorporated against the effect, or the foreseeable possibility of the effect, of a product which can cause that material to die.

37 The use of a herbicide on soy meal is not, however, foreseeable, or even normally conceivable. Moreover, even if it was used in that way, a patented product intended to protect the life of biological material containing it could not perform its function, since the genetic information can be found only in a residual state in the soy meal, which is a dead material obtained after the soy has undergone several treatment processes.

38 It follows from the foregoing that the protection provided for in Article 9 of the Directive is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived.

39 It also follows that that protection cannot be relied on in relation to the material in question on the sole ground that the DNA sequence containing the genetic information could be extracted from it and perform its function in a cell of a living organism into which it has been transferred. In such a scenario, the function would be performed in a material which is both different and biological. It could therefore give rise to a right to protection only in relation to that material.

40 To allow protection under Article 9 of the Directive on the ground that the genetic information performed its function previously in the material containing it or that it could possibly perform that function again in another material would amount to depriving the provision interpreted of its effectiveness, since one or other of those situations could, in principle, always be relied on.

41 Monsanto argues, however, that its principal claim is for protection of its patented DNA sequence as such. It explains that the DNA sequence at issue in the case in the main proceedings is protected by the applicable national patent law, in accordance with Article 1(1) of the Directive. Article 9 of the Directive relates solely to an extension of such protection to other material in which the patented product is incorporated. In the case in the main proceedings, Monsanto is not, therefore, seeking to obtain the protection provided for by Article 9 of the Directive for the soy meal in which the patented DNA sequence is incorporated. This case concerns the protection of the DNA sequence as such, which is not linked to the performance of a specific function. Such protection is indeed absolute under the applicable national law, to which Article 1(1) of the Directive refers.

42 Such an analysis cannot be accepted.

43 In that regard, it should be borne in mind that recital 23 in the preamble to the Directive states that 'a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention'.

44 Moreover, the import of recitals 23 and 24 in the

preamble to, and Article 5(3) of the Directive is that a DNA sequence does not enjoy any protection under patent law when the function performed by that sequence is not specified.
45 Since the Directive thus makes the patentability of a DNA sequence subject to indication of the function it performs, it must be regarded as not according any protection to a patented DNA sequence which is not able to perform the specific function for which it was patented.
46 That interpretation is supported by the wording of Article 9 of the Directive, which makes the protection it provides for subject to the condition that the patented DNA sequence performs its function in the material in which it is incorporated.
47 An interpretation to the effect that, under the Directive, a patented DNA sequence could enjoy absolute protection as such, irrespective of whether or not the sequence was performing its function, would deprive that provision of its effectiveness. Protection accorded formally to the DNA sequence as such would necessarily in fact extend to the material of which it formed a part, as long as that situation continued.
48 As follows from paragraph 37 of this judgment, a DNA sequence such as that at issue in the main proceedings is not able to perform its function when it is incorporated in a dead material such as soy meal.
49 Such a sequence does not, therefore, enjoy patent right protection, since neither Article 9 of the Directive nor any other provision thereof accords protection to a patented DNA sequence which is not able to perform its function.
50 Accordingly, the answer to the first question is that Article 9 of the Directive must be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it was patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.

The second question

51 By its second question, the national court asks, essentially, whether Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.
52 That question is based on the premise, referred to in the order for reference, that a national provision such as Article 53 of the 1995 Law does in fact accord absolute protection to the patented product.
53 In order to answer the second question, it is appropriate to note that, in recitals 3 and 5 to 7 in the preamble to the Directive, the Community legislature states that:
– effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;
– differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States;
– such differences could create barriers to trade and hence impede the proper functioning of the internal market;
– such differences could well become greater as Member States adopt new and different legislation and administrative practices, or national case-law interpreting such legislation develops differently;
– uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market.
54 Recitals 8 and 13 in the preamble to the Directive further state that:
– legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law;
– the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;
– the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply, inter alia, to the patentability of biological material as such and to the scope of protection conferred by a patent on a biotechnological invention.
55 It follows from those statements that the Community legislature intended to effect a harmonisation which was limited in its substantive scope, but suitable for remedying the existing differences and preventing future differences between Member States in the field of protection of biotechnological inventions.
56 The harmonisation decided upon is thus aimed at avoiding barriers to trade.
57 Moreover it represents a compromise between the interests of patent holders and the need for proper functioning of the internal market.
58 As regards, in particular, Article 9 of the Directive, found in Chapter II, entitled 'Scope of protection', the Community legislature's approach reflects its intention to ensure the same protection for patents in all Member States.
59 Uniform protection appears to be the means to eliminate or prevent differences between the Member States and to obtain the desired balance between the interests of patent holders and those of other operators whereas, conversely, a minimalist harmonisation approach which would favour patent holders would, on the one hand, compromise the balance sought between the interests at stake and, on the other hand, only entrench or give rise to differences between the Member States, thereby fostering barriers to trade.

60 It follows that the harmonisation effected by Article 9 of the Directive must be regarded as exhaustive.
61 The first sentence of Article 1(1) of the Directive does not militate against such a conclusion inasmuch as it refers to national patent law for the protection of biotechnological inventions. The second sentence of Article 1(1) states that, if necessary, Member States are to adjust their national patent law to take account of the provisions of the Directive, that is, in particular, those effecting exhaustive harmonisation.
62 Accordingly, in so far as the Directive does not accord protection to a patented DNA sequence which is not able to perform its function, the provision interpreted precludes the national legislature from granting absolute protection to a patented DNA sequence as such, regardless of whether it performs its function in the material containing it.
63 The answer to the second question is therefore that Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.

The third question

64 By its third question, the national court asks, essentially, whether Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.
65 Like the second question, the third is based on the premise that a national provision such as Article 53 of the 1995 Law did in fact accord absolute protection to the patented product when the patent was issued prior to the Directive.
66 In order to answer that question, it must be borne in mind that, according to settled case-law, new rules apply, as a matter of principle, immediately to the future effects of a situation which arose under the old rule (see, inter alia, Case C-334/07 P Commission v Freistaat Sachsen [2008] ECR I-9465, paragraph 43, and case-law cited).
67 The Directive does not provide for any derogation from that principle.
68 Moreover, non-application of the Directive to patents granted earlier would give rise to differences in protection as between Member States, which would impede the harmonisation sought.
69 The answer to the third question is therefore that Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.

The fourth question

70 By its fourth question, the national court asks, essentially, whether Articles 27 and 30 of the TRIPS Agreement affect the interpretation given of Article 9 of the Directive.
71 In that regard, it should be borne in mind that the provisions of the TRIPS Agreement are not such as to create rights upon which individuals may rely directly before the courts by virtue of European Union law (**Joined Cases C-300/98 and C-392/98 Dior and Others [2000] ECR I-11307**, paragraph 44).
72 If it should be found that there are European Union rules in the sphere in question, European Union law will apply, which will mean that it is necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to the provision of that agreement at issue (**Case C-431/05 Merck Genéricos - Produtos Farmacêuticos [2007] ECR I-7001, paragraph 35**).
73 Since the Directive constitutes European Union rules in the sphere of patents, it must therefore, as far as may be possible, be interpreted in such a manner.
74 It is clear that the interpretation given in the present judgment of Article 9 of the Directive does not run counter to that obligation.
75 Article 9 of the Directive governs the scope of the protection conferred by a patent on its holder, whilst Articles 27 and 30 of the TRIPS Agreement concern, respectively, patentability and the exceptions to the rights conferred by a patent.
76 On the assumption that 'exceptions to rights conferred' could be regarded as encompassing not only exclusions of rights but also limitations on those rights, it should be pointed out that an interpretation of Article 9 of the Directive limiting the protection it confers to situations in which the patented product performs its function does not appear to conflict unreasonably with a normal exploitation of the patent and does not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties', within the meaning of Article 30 of the TRIPS Agreement.
77 The answer to the fourth question is therefore that Articles 27 and 30 of the TRIPS Agreement do not affect the interpretation given of Article 9 of the Directive.

Costs

78 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.
On those grounds, the Court (Grand Chamber) hereby rules:
1. Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organ-

ism.
2. Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.
3. Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.
4. Articles 27 and 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) do not affect the interpretation given of Article 9 of the Directive.
[Signatures]

Opinion of Avocate General P. Mengozzi
delivered on 9 March 2010 (1)
Case C-428/08
Monsanto Technology LLC
v
Cefetra BV and Others
(Reference for a preliminary ruling from the Rechtbank 's-Gravenhage (Netherlands))
(Legal protection of biotechnological inventions – Directive 98/44/EC – Patent for genetic information)
1. The Court has so far had few opportunities to concern itself with the directive on the legal protection of biotechnological inventions. The present case, however, will give the Court a chance to clarify a number of important points relating to the protection which must be recognised, within the European Union, as accruing to patents awarded within the field of biotechnology, the significance of which cannot nowadays be underestimated.

I – Legislative framework
A – The TRIPS Agreement
2. Articles 27 and 30 of the Agreement on Trade-related Aspects of Intellectual Property Rights (2) ('the TRIPS Agreement') provide as follows:
'Article 27
Patentable Subject Matter
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
…
Article 30
Exceptions to Rights Conferred Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'
B – Directive 98/44/EC
3. The recitals in the preamble to Directive 98/44/EC (3) contain the following statements:
'…
(3) … effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;
…
(5) … differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; … such differences could create barriers to trade and hence impede the proper functioning of the internal market;
(6) … such differences could well become greater as Member States adopt new and different legislation and administrative practices, or … national case-law interpreting such legislation develops differently;
(7) … uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;
(8) … legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; … the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of

technological developments involving biological material which also fulfil the requirements for patentability;
…
(22) … the discussion on the patentability of sequences or partial sequences of genes is controversial; … according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; … the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;
(23) … a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;
(24) … in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;
…'.
4. Article 1 of Directive 98/44 provides:
'1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive. 2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.'
5. The following provision is laid down in Article 5 of Directive 98/44:
'…
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.'
6. Article 9 of Directive 98/44 states:
'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.'

C – National legislation

7. The Netherlands Law on patents (Rijksoctrooiwet 1995; 'the ROW95'), as subsequently amended, transposes Article 9 of Directive 98/44 into national law in the following terms:
'Article 53a
…
3 In respect of the patent for a product containing or consisting in genetic information, the exclusive right shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function, subject to Article 3(1)(b).'

II – Facts, the proceedings before the national court and the questions referred

8. Monsanto is the holder of the European patent ('the patent') issued on 19 June 1996 for a DNA sequence which, when introduced into the DNA of a soya plant, makes that plant resistant to Glyphosate, a herbicide produced by the same company and marketed under the name 'Roundup'.
9. The genetically modified soya plants, known as 'RR soya' (that is to say, 'Roundup-ready soya'), are cultivated in various countries over the world but not in the territory of the European Union ('EU territory'). The advantage of using genetically modified soya is that it enables the growers to use the Roundup herbicide to destroy invading weeds without fear of damaging the soya crop.
10. In Argentina, RR soya is cultivated on a vast scale and is an important export product. However, for reasons relating to Argentinian law, Monsanto does not hold a patent in Argentina for the DNA sequence characteristic of the RR soya plant.
11. In 2005 and 2006, the defendant companies in the case before the Rechtbank 's-Gravenhage (District Court, The Hague; 'the referring court') imported a number of soy meal consignments from Argentina. At the request of Monsanto, samples of that meal were analysed, revealing the presence of traces of the DNA characteristic of RR soya. It was thus established that the imported soy meal, which was unloaded in the port of Amsterdam and intended for the production of animal feed, had been produced in Argentina from genetically modified soya for which Monsanto holds the European patent.
12. Since Monsanto considered the importing companies liable for infringing its patent, it brought proceedings against them before the referring court.
13. On the view that the interpretation of Directive 98/44 was necessary for the purposes of adjudicating the dispute, the referring court stayed proceedings and referred the following questions to the Court for a preliminary ruling:
'(1) Must Article 9 of Directive 98/44 … be interpreted as meaning that the protection provided under that provision can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism?
(2) Proceeding on the basis that the DNA sequence described in claim 6 of [the] patent … is present in the soy meal imported into the Community by Cefetra and ACTI, and that the DNA is incorporated in the soy meal for the purposes of Article 9 of Directive 98/44 and that it does not perform its function therein: does the protection of a patent on biological material as provided for under Directive 98/44, in particular under Article 9 thereof, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether that DNA performs its function, and must the protection as provided under Article 9 of Directive 98/44 therefore be deemed to be exhaustive in the situation

referred to in that provision, in which the product consists in genetic information or contains such information, and the product is incorporated in material which contains the genetic information?
(3) Does it make any difference, for the purposes of answering the previous question, that [the] patent … was applied for and granted (on 19 June 1996) prior to the adoption of Directive 98/44 and that such absolute product protection was granted under national patent legislation prior to the adoption of that directive?
(4) Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?'

III – Preliminary considerations

14. In the case before the referring court, as is clear from the brief summary of the facts, Monsanto is acting solely against importers of soy meal originating in Argentina. The reason for this – as Monsanto itself acknowledged – is that Monsanto does not enjoy patent protection for RR soya in Argentina. By contrast with Argentina, Monsanto receives a royalty in other soya-producing countries, such as Brazil, for the use of its invention, owing to the protection secured by the patent or to agreements with growers.
15. None the less, it should be pointed out that the decision to limit the judicial proceedings in EU territory to products originating in Argentina is a simple matter of commercial policy for Monsanto. If the Court were to hold that Monsanto may, within EU territory, rely on rights relating to soy meal originating in Argentina, there would be nothing to prevent Monsanto, subsequently, from asserting analogous rights in relation to soy meal from other countries. The principle of exhaustion, in fact, does not apply until after the first entry of a product into EU territory with the consent of the patent holder. (4)
16. Accordingly, the interpretation that the Court is required to give will apply generally in all cases in which a product imported into EU territory is derived from the processing, in a non-Member State, of a genetically modified plant in respect of which there is a patent valid in EU territory.

IV – Question 1

A – Preliminary observations

17. By Question 1, clarification is sought from the Court as to whether, in a case such as that before the referring court, Article 9 of Directive 98/44 protects Monsanto's position even in a situation where the DNA sequence is not currently performing its function, but has performed that function in the past or may do so in the future.
18. At first glance, this question could be understood as relating only to the verb tense used in Article 9 of Directive 98/44, under which – as has been seen – the protection provided for in that provision is assured only if the genetic information 'performs its function'. If that interpretation of the question were correct, it could simply be pointed out by way of reply that, since it is the present tense that is used in the legislative provision in question, the fact that the patented DNA sequence has performed its function in the past or may do so in the future is wholly irrelevant. (5) For the purposes of deciding whether Article 9 is applicable at any given moment, consideration must be given to the circumstances of that particular moment. Only the 'present' performance of the function can trigger the application of that provision. At a time when the function is not being performed, Article 9 cannot be infringed: naturally, if and when the DNA sequence resumes performance of its function, the protection under Article 9 will revive.
19. That is the general thrust of the replies to Question 1 suggested by the various parties which submitted observations, with the exception of Monsanto. And that is how I propose that the Court should reply to the national court, should the Court wish to address the question in the restrictive terms that I have indicated.
20. It is my belief, however, that to interpret the question narrowly would be a mistake and that, in order to provide the national court with an appropriate reply, it is necessary to interpret Article 9 in the context of Directive 98/44 as a whole and of the protection conferred by it on patents for biotechnological inventions. Nor, moreover, should it be forgotten that, in its written observations and at the hearing, Monsanto dwelt on the fact that, in its view, the patent protection which it has the right to assert does not stem from Article 9 of Directive 98/44 but from the 'classic' protection which, under traditional patent law and the terms of Directive 98/44 itself, must be recognised as accruing to the DNA sequence as such. According to Monsanto, in other words, it is the DNA sequence, understood as a chemical substance, which forms the subject-matter of its claim before the Netherlands courts. Monsanto maintains that it is not advancing any claim relating to the soy meal: if the patented DNA were no longer contained in the meal, Monsanto would have no reason, it states, for taking action against the importing companies.

B – Purpose-bound patent protection

21. Thus, the true question to be resolved in order to give a complete reply to the questions raised by the national court is whether, in a case such as this, traditional patent protection exists for genetic information as such. Accordingly, it must be determined whether the genetic information is protected as a chemical compound, even when it is located as a kind of 'residue' within a product resulting from the processing of the biological product (in this case, the soya plants) in which the sequence performed its function.
22. It could be tempting to regard that problem as irrelevant, on the view that the subjectmatter of the dispute before the referring court is simply the soy meal, and not the DNA as such, which is incorporated in the meal. However, that approach does not seem to me to be satisfactory: from a physical point of view, in fact, there is no doubt that the DNA covered by the patent can be detected within the meal and that it, too, was imported into EU territory.
23. With the exception of Monsanto and the Italian Government, the parties which submitted observations did not express a view on that specific issue, even after

being invited at the hearing to do so. Their attention was focussed solely on the soy meal.

24. Monsanto argues – as has been seen – that, whether or not the soy meal is protected (and Monsanto is not claiming that it is), the protection guaranteed by the patent covers the DNA sequence as such. That protection is not derived from Article 9 of Directive 98/44 but from the general provisions of that directive, which are without prejudice to the ordinary law of patents. Article 9 serves merely to extend that basic protection, in specific circumstances. Independently of the applicability of Article 9, however, the basic protection of the DNA sequence as such continues.

25. The Italian Government, on the other hand, argues that, as soon as a DNA sequence is inside another material, the classic patent protection no longer obtains and the only protection applicable – provided that the pre-conditions are met – is the protection of the 'incorporating' materials pursuant to Article 9.

26. However interesting the argument put forward by the Italian Government, I am unable to agree. It should be observed that, generally speaking, Directive 98/44 operates in parallel with the pre-existing law on patents. I would refer in that connection, for example, to recital 8 in the preamble to that directive. It is true that, under Article 1 of Directive 98/44, national patent laws must be amended if that is necessary to bring them into line with the specific provisions of the Community legislation in question. However, there is no textual support for the interpretation contended for by the Italian Government. Nor should it be forgotten that, on the basis of the ordinary law on patents, the fact that an invention is incorporated within another product does not, generally speaking, mean that the protection conferred on the invention comes to an end.

27. On the contrary, it seems to me irrefutable that Article 9 of Directive 98/44 is a rule for the extension of patent protection. That provision is based on the assumption that the patented DNA is protected as such, and extends that protection to cover also, in certain circumstances, the 'material' in which the DNA sequence is contained, provided that the DNA information is performing its function. Since it is common ground that, being only a residue, the patented DNA sequence does not perform any function within the soy meal, the additional protection under Article 9 cannot be relied on in the present case.

28. None the less it remains to be seen whether, in these circumstances, the DNA sequence is protected as such under the general provisions of patent law, as Monsanto maintains. Specifically, it is necessary to determine the circumstances in which a patented DNA sequence is protected as a self-standing product.

29. I consider that, in accordance with the wording and aims of Directive 98/44, a DNA sequence must be regarded as protected, even as a self-standing product, only where it performs the function for which it was patented. In other words, it seems to me that Directive 98/44 permits – and, in fact, requires – an interpretation to the effect that, in EU territory, the protection conferred on DNA sequences is a 'purpose-bound' protection. Even though the directive does not expressly indicate that the protection to be conferred on DNA sequences must be of that order, many elements connected with the overall system of patents for biotechnological products militate in favour of that interpretation.

30. In the first place, various provisions of Directive 98/44 highlight the fact that, in order to be able to obtain a patent relating to a DNA sequence, it is necessary to specify the function performed by that sequence. I would refer in that connection to recitals 22, 23 and 24 in the preamble to the directive, as well as to Article 5(3). Admittedly, those parts of the directive concern the scope of patentability rather than the scope of the protection for the patented product. However, they are not insignificant indices that, from the perspective of the European Union legislature ('the EU legislature'), a DNA sequence has no importance in the context of patents if the function performed by that sequence is not indicated.

31. The great importance attached by Directive 98/44 to the function performed by a DNA sequence is naturally intended to permit a distinction to be drawn between 'discovery' and 'invention'. The isolation of a DNA sequence without any indication of a function constitutes a mere discovery and as such is not patentable. Conversely, the sequence is transformed into an invention, which can then enjoy patent protection, through the indication of a function that it performs. However, to maintain that a DNA sequence enjoys 'traditional' patent protection – that is to say, protection extending to all the possible functions of the sequence itself, including those not identified at the time when the patent is applied for – would mean that patents would be recognised as covering functions as yet unknown at the time of the patent application. In other words, lodging an application for a patent for a single function of a DNA sequence is all it would take to obtain protection for all the other possible functions of the same sequence. In my view, such an interpretation would ultimately, in practice, make a mere discovery patentable, in breach of the basic principles on patents.

32. Nor should it be forgotten that, as a matter of principle, the essential nature of a patent consists in a genuine exchange. On the one hand, the inventor makes public his own invention, thereby enabling the general public to benefit from it. In exchange, the inventor enjoys exclusive property rights over the invention itself for a limited period of time. It seems to me that to grant absolute protection to an invention consisting in a DNA sequence, thereby conferring on the patent holder exclusive rights over that sequence, extending to all its possible uses, including those unspecified or unknown at the time when the application was lodged, would be in breach of that fundamental principle, in so far as it would confer on the patent holder a disproportionate level of protection.

33. It should also be observed that, if the approach argued for by Monsanto were followed, Article 9 of Directive 98/44 would be deprived of useful effect as a provision for extending patent protection. If, in fact, the

DNA sequence were intended to enjoy protection as such even when not performing its function, it is difficult to see why Article 9 would have to make extension of protection conditional upon the sequence performing its function. In practice, whether or not the DNA sequence performed that function, protection would be guaranteed in any event by the mere presence of the sequence, as in the present case. The fact that Monsanto claims protection for the sequence and not for the soy meal does not alter the fact that, in concreto, the protection is also effective with regard to the meal.

34. It seems to me that the interpretation proposed by Monsanto would ultimately lead the holder of a biotechnological patent to be granted too wide a range of protection. In fact, as was stated by some of the parties either in written observations or at the hearing, it is not possible to say for how long, or up to which stage of the food and derived product chain, traces of the original DNA of the genetically modified plant are still identifiable. Plainly, those sequences no longer perform any function, but their very presence means that an unspecified number of derivative products would come under the control of the person who had patented the DNA sequence of a plant. As the Argentine Government pointed out, following a line of reasoning that is paradoxical only in part, if traces of the sequence were to be detected in the stomachs of cattle because the animals had been fed with products derived from the genetically modified plant, even the importation of those cattle could be regarded as an infringement of the patent-holder's rights. (6)

35. There is no doubt that the lack of protection for Monsanto's invention in Argentina seems unfair. By the same token, however, and leaving aside the reasons for that lack of protection, it seems to me that Monsanto's plan of action is to try to use one legal order (that of the European Union) to remedy problems encountered in another legal order (that of Argentina). That seems to me, however, to be unacceptable. The fact that Monsanto cannot obtain adequate remuneration for its patents in Argentina cannot be remedied by according Monsanto extended protection in the European Union.

36. As is generally known, purpose-bound protection does not mark an entirely novel approach in the field of biotechnology. More specifically, with regard to the matters covered by Directive 98/44, both the French and the German legislature have opted for that type of protection, albeit solely in respect of DNA sequences relating to the human body. (7) The European Parliament, too, has adopted a resolution in which it advocates purpose-bound protection for patents relating to human DNA. (8) Moreover, in the context of patents relating to chemical substances, the settled practice is that, where a substance has already been patented in respect of certain uses, it is recognised as patentable in respect of a new, different use. (9)

37. Some clarification is necessary on that point. To limit patent protection of DNA sequences to the functions for which the patent was obtained, in accordance with the purpose-bound protection model, does not mean limiting protection to cases in which the patented gene is 'switched on'. In fact, from a biological point of view, there are genes which are 'switched on' only in certain circumstances: for example, as emerged at the hearing, a gene which makes a plant particularly resistant to drought becomes active only in the event of drought. Plainly, for the purposes of Directive 98/44, the fact that the gene 'performs its function' within the meaning of Article 9 does not mean that it is 'switched on'. Under the directive, a DNA sequence 'performs its function' when:

(i) it is within live matter of which it forms part; (ii) it is transmitted when the live matter reproduces itself; and (iii) it performs the function for which it was patented, either continuously or on the occurrence of specified circumstances.

38. It should be added that, in any event, the clarification made in point 37 above is of no relevance to the present case, since it is common ground that, in RR soya plants, the DNA sequence in question is permanently 'switched on'.

C – The residual nature of the DNA contained in the soy meal

39. An alternative approach to that set out above would be to take the view that, in the imported soy meal, the DNA covered by the patent constitutes merely a residue, of which only traces are present and which does not therefore warrant protection. From that perspective, Monsanto's claim would in reality concern the meal and not the DNA sequence. Its claim to traditional protection for the sequence as such would serve merely as a pretext.

40. However, that approach does not seem to me to be practicable. There is no de minimis provision in Directive 98/44 to limit or exclude protection relating to DNA sequences which are present only in variable quantities (and/or extremely small quantities) in a product derived from biological material. (10) In other words, to go down that interpretative route would mean introducing an element of quantitative evaluation (what would be the reference threshold?) not provided for in Directive 98/44, which could lead ultimately to greater uncertainty. To limit the protection of DNA sequences to the purpose for which they were patented is, to my mind, an approach that is preferable from all points of view.

D – Conclusion on Question 1

41. Thus, concluding my analysis of Question 1, I propose that, by way of answer, the Court should declare that, under the system established by Directive 98/44, the protection for a patent relating to a DNA sequence is limited to the situations in which the genetic information is currently performing the functions described in the patent. That holds true both as regards the protection of the genetic information as such and as regards the protection of the materials in which the genetic information is contained.

V – Question 2

42. By Question 2, the referring court is essentially asking whether Directive 98/44 precludes national legislation from offering, in relation to biotechnological inventions, patent protection wider than that provided

for under the directive itself.
43. In other words, it is necessary to determine whether the rules laid down in Directive 98/44 are exhaustive or minimal with regard to patents in the biotechnological sector. If they are exhaustive, national legislation conferring protection wider than that provided for under the directive would be unlawful; if they are minimal, on the other hand, it could be acceptable.
44. The question is based, of course, on the assumption that the national rules actually offer patent holders wider protection than Directive 98/44. That is a matter for the national courts to determine. It follows that, even though, in the case before the referring court, the rules laid down in the Netherlands legislation appear almost identical to those laid down in Directive 98/44 – even with regard to the linguistic terms in which they are framed – with the result that the allegedly greater protection is difficult to discern, the assumption that the protection is in fact greater must be accepted for present purposes.
45. On Question 2 as well, the position argued for by Monsanto is isolated from that of all the other parties which submitted observations. Whilst Monsanto maintains that Directive 98/44 could not, in any case, limit the freedom of the national legislature in the various Member States with regard to the specific point at issue here, all the other parties are inclined to regard Directive 98/44 as laying down an exhaustive body of rules.
46. An initial observation that I consider necessary concerns the fact that the body of rules laid down in Directive 98/44 with regard to patents in the biotechnological sector is manifestly incomplete. Various aspects are left to the national legislature. Moreover, clear evidence to that effect is provided in recital 8 in the preamble to Directive 98/44, which reaffirms the role played by national laws, and the central nature of that role.
47. Nevertheless, the fact that the rules are incomplete does not mean that they are not exhaustive. In fact, it is perfectly conceivable that, even though a EU legislative measure does not cover all aspects of a given sector, the system established by that measure is exhaustive with regard to the particular matters dealt with. In such a case, the freedom of the national legislature in the various Member States is limited to the areas in which the EU legislature has not intervened. (11)
48. In my view, the situation in relation to biotechnological patents dovetails exactly with the framework outlined in point 47 above. The body of rules laid down in Directive 98/44 is not complete, but must be deemed to be exhaustive in the areas with which it deals: the corollary being that, in those areas, national legislation cannot provide for a level of patent protection which is wider than that provided for under the directive.
49. The reasons in support of that interpretation are manifold.
50. First, the fundamental objective of Directive 98/44 is to promote the market and competition, albeit while respecting and safeguarding the investments made by patent-holders. That is clear both from the legal basis for Directive 98/44 (at the time of its adoption, Article 100a of the Treaty, corresponding to the current Article 114 TFEU) and from its content (see, for example, recital 5). It goes without saying, it seems to me, that the conferring of particularly generous rights on patent holders would potentially run counter to that objective since, by definition, a patent constitutes a restriction on economic freedom. (12)
51. Moreover, a study of some of the recitals in the preamble to Directive 98/44 – in particular, recitals 3, 5, 6 and 7 – clearly shows that the main concern of the legislature was not so much to increase the protection of biotechnological inventions, but rather to prevent existing legislative differences in that area from having a negative effect on trade within the European Union. Plainly, to construe Directive 98/44 as an instrument for minimal harmonisation, with the attendant possibility of wide legislative divergences between the Member States, would conflict with that fundamental objective. The existence, within the European Union, of different levels of protection for the same patents would ultimately be an inconvenience and a source of uncertainty for the patent-holders themselves.
52. It should also be observed that there is nothing explicit in Directive 98/44 to support the inference that the Member States are free to grant wider protection than that provided for under that directive. In rules introducing minimal harmonisation, a provision of that type is frequently inserted, as the United Kingdom, in particular, correctly pointed out in its written observations. (13)
53. Moreover, directives which provide for minimal harmonisation are typically intended to secure protection that was previously non-existent. Here, on the contrary, the problem that the legislature sought to resolve – or, at any rate, to attenuate – consisted in the existing divergences in that area between national legal systems. (14)
54. In summing up, I would also like to highlight an important aspect. Generally speaking, the very idea of minimal harmonisation is hardly practicable with regard to patents. As a general rule, measures providing for minimal harmonisation are adopted in circumstances in which certain persons are clearly in a position of weakness or inferiority in relation to others. Typical examples of this are the cases, already referred to, of consumers who enter into distance contracts or workers who are affected by collective dismissal. (15) It is clear, in such situations, in which direction the wider protection would incline: it would inevitably incline towards those in a weaker position.
55. In the field of patents, however, matters are not so unequivocal. The ‘commercial’ nature of the patent, as an exclusive property right conferred in exchange for the disclosure of information and knowledge by the inventor, precludes the involvement of a person who is ‘weaker’ or ‘more deserving of protection’. By definition, a patent is a legal instrument which seeks to strike a balance between two conflicting interests: on the one hand, the interest in disclosure and in the progress of knowledge and, on the other, the interest in the promo-

tion of investment and the fostering of creativity. As a consequence, even if Directive 98/44 were to be construed as introducing a level of minimum protection, no foregone conclusion would be possible as to whether the 'more protective' national rules should safeguard the patent holders or the free movement of ideas (and goods).

56. For all the reasons set out above, I propose that the Court state in reply to Question 2 that, for the areas with which it deals, Directive 98/44 constitutes an exhaustive body of rules governing the protection to be recognised in the European Union as accruing to a biotechnological invention. As a consequence, it precludes national legislation from conferring on biotechnological inventions protection which is wider than that provided for under that directive.

VI – Question 3

57. By Question 3, the referring court seeks clarification from the Court as to the treatment to be accorded, following the entry into force of Directive 98/44, to a patent awarded earlier which enjoys protection wider than that provided for under the directive.

58. In this connection, too, Monsanto is alone in maintaining that the date of the award of the patent can be relevant for the purposes of determining the breadth of protection to be accorded to that patent. Moreover, Monsanto puts forward that argument, by way of a lesser alternative, in the event that the Court declines to uphold Monsanto's position on the preceding questions.

59. In my view, two things must be borne in mind before this question can be answered.

60. First, as with Question 2, it is necessary to start from the assumption – even if this is not clearly demonstrated – that, at the time when the patent was awarded, its scope was in fact wider than the scope of a patent under Directive 98/44.

61. Secondly, even though the question is couched in rather general terms, it must always be construed in the context of the specific national proceedings pending before the national court. In other words, the question must be understood as referring to a case with the same clearly defined characteristics as the dispute between Monsanto, the company which is the holder of the European patent for the DNA sequence relating to RR soya, and a number of companies which import soy meal originating in Argentina into the Netherlands.

62. A factor of great importance is to be inferred from that second condition. What Monsanto is claiming is not simply patent protection corresponding to the claims contained in the patent application relating to the DNA sequence characteristic of RR soya. The claims refer to the DNA sequence designed to create resistance to Glyphosate herbicide. There is indeed no doubt that, if the sequence guarantees such resistance (thus performing its function), it is deserving of protection under Directive 98/44.

63. However, in the present case, Monsanto is also claiming protection for the sequence when it is not performing its function, and is incorporated, as residue, in dead matter (the soy meal). Consequently, if the Court were to declare that the date on which a patent is awarded is irrelevant for the purposes of determining the protection accruing to that patent under Directive 98/44, in no event would there be a reduction in the protection of the subject-matter of the claims (the sequence which produces a certain effect). The only factor to change would be the extension of the 'additional' protection conferred by the patent.

64. In my view, the date of award of the patent must be regarded, in the present case, as irrelevant. On that point – as with the preceding questions referred, for that matter – there is no express and unequivocal answer to be found in Directive 98/44. None the less, various elements militate in favour of that view.

65. First, Directive 98/44 does not contain any transitional provisions. If the legislature had wished to safeguard the situation of pre-existing patents, it would probably have inserted specific provisions in the legislative text.

66. Secondly, it should be borne in mind that the Court has consistently held that the obligation to interpret national law in conformity with the law of the European Union applies also to provisions of national law which pre-date the relevant EU provisions. (16) Moreover, the present case does not concern an area in which an interpretation of earlier provisions consistently with EU law could have consequences connected with criminal liability: if it did, to construe them in that way would probably be an unacceptable misapplication of the rules of interpretation. (17)

67. Thirdly, and lastly, it should be borne in mind that, as has been seen above, Directive 98/44 was drawn up with the principal objective of promoting the market and competition in EU territory. Given that context, to interpret that directive in such a way as to accommodate an interpretation of patents which varied according to the date of their award would cause problems. To construe the legislation in that way would ultimately create significant problems for the free movement of goods and the attainment of an efficient single market in the sector. In particular, legal certainty would be seriously undermined if the precise scope of a patent fell to be delimited by reference, not to the claims for which it was awarded, but to the date of the award. That is not to mention the fact that, since such 'broad' interpretations are, at most, a feature of only some of the legal systems of the Member States, the effect of recognising such interpretations as legitimate under Directive 98/44 would be that, for many years to come, and, specifically, until the expiry of the patents which were valid at the time when the directive entered into force, major differences would continue to exist between the levels of protection in the various Member States.

68. I therefore propose that, in reply to Question 3, the Court should state that the fact that a patent was awarded before the entry into force of Directive 98/44 has no bearing on the answers to be given to Questions 1 and 2.

VII – Question 4

69. By Question 4, the Court is asked to indicate

whether, for the purposes of the reply to be given to Questions 1, 2 and 3, the TRIPS Agreement and, specifically, Articles 27 and 30 of that agreement, have a role to play.

70. I would say straight away that I share the view expressed in this connection by all the parties, with the exception of Monsanto, to the effect that the TRIPS Agreement cannot in any way alter the reply to be given to the first three questions. In particular, the interpretation of Directive 98/44 that I am proposing does not, in my opinion, conflict in any way with the content of Articles 27 and 30 of the TRIPS Agreement.

71. In any event, it should be borne in mind at the outset that Article 1 of Directive 98/44 expressly provides that the provisions of the directive are without prejudice to the obligations imposed on Member States under the TRIPS Agreement. This means that the legislature took the view that there was nothing in Directive 98/44 which was incompatible with the international treaty in question: in any event, it follows from the express safeguard clause laid down in Article 1 of the directive that a Member State can never be accused of infringing Directive 98/44 where, by its conduct, that Member State is seeking to comply with its obligations under the TRIPS Agreement.

72. It is clear that, in these circumstances, the most effective interpretative method, if conflicts between Directive 98/44 and the TRIPS Agreement are to be avoided, is to interpret the directive as far as possible in a manner consistent with the provisions of the TRIPS Agreement. More generally speaking, for that matter, it should be borne in mind that while, on the one hand, the case-law of the Court precludes the possibility of testing the lawfulness of a provision of EU law against the yardstick of WTO agreements, (18) on the other hand, it affirms the need to avoid possible conflicts by applying the principle of consistent interpretation. (19)

73. It must therefore be determined whether the interpretation of Directive 98/44 that I have proposed above could conflict with provisions of the TRIPS Agreement: in my view, there is no possible conflict.

74. There is nothing in the rules laid down in the TRIPS Agreement to preclude purpose-bound protection for patents relating to DNA sequences.

75. Specifically, Article 27 of the TRIPS Agreement is concerned exclusively with patentability. In the present case, no problem of patentability arises, since it is not disputed that Monsanto has the right – which it has actually exercised – to patent the DNA sequence which makes soya resistant to Glyphosate. The point of contention between the parties is merely the extent of the protection which must be recognised as accruing to the invention.

76. Nor are there problems of compatibility with Article 30 of the TRIPS Agreement, which concerns possible exceptions to the rights conferred on a patent holder. Above all, in fact, to recognise purpose-bound protection does not mean providing for exceptions from the scope of protection of a patent: what is defined in narrow terms rather, is the extent of the right itself, which is not recognised in respect of uses other than those described in the patent application. There is no obligation under the TRIPS Agreement to recognise that the protection accruing to DNA sequences is 'absolute' – that is to say, protection in respect of all possible uses, including even unforeseen and future uses.

77. Moreover, even if it were sought to maintain, ad absurdum, that purpose-bound protection of DNA sequence patents constitutes a limitation of the scope of a patent in accordance with Article 30 of the TRIPS Agreement, it seems to me that that could still be entirely acceptable. Article 30 in fact requires exceptions to be 'limited' and not to impede the 'normal exploitation' of the invention. However, to limit the protection of a DNA sequence to the uses for which it was patented certainly does not prevent the normal exploitation of the invention, as described in the patent application. By definition, in fact, protection is ruled out only for future and unforeseeable uses (which, in any event, could in their turn be patented by the holder of the first patent if he discovers them) or, as in the present case, for activities connected with the processing of the original product, in the context of which the DNA sequence no longer performs any function.

78. I therefore propose that it be stated in reply to Question 4 that the provisions laid down in the TRIPS Agreement do not conflict with Directive 98/44, as interpreted in accordance with the proposed answers to Questions 1, 2 and 3.

VIII – Conclusion

79. On the basis of the foregoing considerations, I propose that the Court should reply as follows to the questions referred to it by the Rechtbank 's-Gravenhage: Under the system established by Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the protection for a patent relating to a DNA sequence is limited to situations in which the genetic information is currently performing the functions described in the patent. That holds true both as regards the protection of the genetic information as such and as regards the protection of the materials in which that genetic information is contained. In the areas with which it deals, Directive 98/44 constitutes an exhaustive body of rules governing the protection to be recognised in the territory of the European Union as accruing to a biotechnological invention. As a consequence, Directive 98/44 precludes national legislation from offering, in relation to biotechnological inventions, patent protection wider than that provided for under that directive. The fact that a patent was granted before the entry into force of Directive 98/44 has no bearing on the answers to be given to Questions 1 and 2. The provisions laid down in the TRIPS Agreement do not conflict with Directive 98/44, as interpreted in accordance with the proposed answers to Questions 1, 2 and 3.

1 – Original language: Italian.

2 – Approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay

Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1). The text of the TRIPS Agreement is published in the same volume of the Official Journal of the European Communities, at p. 214. The authentic versions of the international agreements of the Uruguay Round are those drawn up in English, French and Spanish.

3 – Directive 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).

4 – The principle of exhaustion is a natural consequence of the prohibition, laid down in the Treaties (currently in Articles 34 TFEU and 35 TFEU), on quantitative restrictions and measures having equivalent effect. For the purposes of that principle, a patent holder who has agreed to the placing on the market of a product in respect of which it enjoys rights by virtue of its patent cannot then challenge subsequent legal transactions (assignment and so on) concerning that product. In fact, in the words of the Court, 'the substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market' (Case 187/80 Merck [1981] ECR 2063, paragraph 9; emphasis added). The case-law on the principle of exhaustion has been reaffirmed by the Court on a number of occasions: see, for example, Joined Cases C-267/95 and C-268/95 Merck and Beecham [1996] ECR I-6285. On the distinction – for the purposes of the application of the principle of exhaustion – between placing on the market outside the European Union and placing on the market within its territory, see, by analogy, Case 51/75 EMI Records [1976] ECR 811, paragraphs 6 to 11.

5 – In fact, the present tense is used in all the language versions of the Directive.

6 – The same could be said, for example, of clothing manufactured from fibres derived from genetically modified cotton plants.

7 – Report of 14 July 2005 from the Commission to the Council and the European Parliament – Development and implications of patent law in the field of biotechnology and genetic engineering, COM(2005) 312 final, paragraph 2.1. The document notes that parts of Directive 98/44 are not entirely unequivocal in this regard.

8 – Resolution of the European Parliament of 26 October 2005 on patents for biotechnological inventions (OJ 2005 C 272 E, p. 440, paragraph 5).

9 – That is the practice typically followed in the sector of pharmaceutical products, in particular. Since a method for treatment is not as such patentable (see, for example, Article 53 of the European Patent Convention signed in Munich on 5 October 1973, as amended in the year 2000), in order to protect the interests of undertakings active in the medical research sector, it has been held that a product is patentable where it is already known, to the extent to which it is intended for a new use (see Board of Appeal, Extended Composition, of the European Patent Office, Decisions G 1/83, G 5/83 and G 6/83 of 5 December 1984 in Bayer and Others). Moreover, the same approach has been adopted outside the pharmaceutical field (see Board of Appeal, Extended Composition, of the European Patent Office, Decision G 2/88 of 11 December 1989 in Mobil).

10 – See, to that effect, the decision of 10 October 2007 by which the High Court of England and Wales, in a case identical to that now pending before the referring court, refused to allow Monsanto to block the importation of soy meal from Argentina: Monsanto v Cargill [2007] EWHC 2257 (Pat), paragraph 89. In that case, Monsanto's claim was rejected on the basis of considerations relating to the extension of the patent claims.

11 – See Case C-52/00 Commission v France [2002] ECR I-3827, paragraph 19.

12 – See, in a similar case, Joined Cases C-281/03 and C-282/03 Cindu Chemicals and Others [2005] ECR I-8069, paragraphs 39 to 44.

13 – See, for example, Article 8 of Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises (OJ 1985 L 372, p. 31) and Article 5 of Council Directive 98/59/EC of 20 July 1998 on the approximation of the laws of the Member States relating to collective redundancies (OJ 1998 L 225, p. 16). See also Commission v France, cited in footnote 11, paragraph 18.

14 – See Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-7079, paragraph 16. See also paragraph 25 of that judgment, in which the Court observes that the directive introduced a series of 'clarifications' and 'derogations' with regard to national laws: this, too, seems hard to reconcile with the notion of a directive providing for a minimum level of harmonisation, which is ordinarily content to set a minimum threshold for protection, leaving the Member States free in other respects.

15 – See footnote 13.

16 – See Case C-106/89 Marleasing [1990] ECR I-4135, paragraph 8; Case C-212/Adeneler and Others [2006] ECR I-6057, paragraph 108; and Case C-188/07 Commune de Mesquer [2008] ECR I-4501, paragraph 84.

17 – See Case C-105/03 Pupino [2005] ECR I-5285, paragraph 45.

18 – The Court has held that, in order for it to be able to examine the lawfulness of a measure adopted by the European Union in the light of a WTO agreement, the European Union must have 'intended to implement a particular obligation assumed in the context of the WTO, or ... the [EU] measure [must] refer ... expressly to the precise provisions of the WTO agreements' (Case C-94/02 P Biret & Cie v Council [2003] ECR I-10565, paragraphs 55 and 56 and the case-law cited).

19 – See Joined Cases C-300/98 and C-392/98 Dior and Others [2000] ECR I-11307, paragraph 47, and Case C-431/05 Merck Genéricos – Produtos Farmacêuticos [2007] ECR I-7001, paragraph 35.