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JUDGMENT 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 incorporated 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-enol-pyruvylshikimate-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 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 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 organism.

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]

* Language of the case: Dutch.

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