***Monsanto v. Cefetra*: EU "Supreme Court" to Interpret Biotech Directive**

Monsanto Technology LLC v. Cefetra B.V., 249983/ HA ZA 05-2885 (Hague District Court 2008), constitutes a first national court referral to the European Court of Justice on the interpretation of the EU Biotech Directive.

The four questions presented (reproduced at page 2 of the attached longer version of this note) focus upon whether the importation into the EU of processed soy meal produced offshore (in Argentina) using an EU patent-protected DNA constitutes an infringement of the patentee's rights under its EU DNA patents. The imported soy meal contains minor amounts of inactive EU-patented DNA.

A complete translation generously provided by Dutch intellectual property lawyer Charles Gielen is also included in the attachment.

Regards,

Hal

April 1, 2008

Questions Proposed for Reference to the European Court of Justice (¶ 4.30)

"This [opinion]… deal[s] with a limitation in the protection for DNA sequences, not so much due to the provisions determining the scope thereof in Articles 8 and 9 of the Directive but due to the requirements the patent application must comply with.… But whatever the implications thereof, the explanation of the Directive is reserved for the ECJ. The Court intends to refer the following questions concerning the explanation of the terms of Article 9 of the Directive before the European Court.

"1. Should Article 9 of the Directive be understood such that the protection meant in this Article can also be relied upon in a situation such as in these proceedings whereby the product (the DNA) is present in a materials and does not express its function at the time of the stated breach but has indeed expressed its function or possibly, following the isolation from the material and its incorporation in the cell of an organism, could once again express its function?

"2. Proceeding from the presence of the DNA sequence as described in claim 6 of the patent in soy meal imported into the European Community by Cefetra and ACTI and assuming that DNA is incorporated in the soy meal as meant in Article 9 of the Directive and that it therein no longer expresses its function:

"Does the provided protection of a patent for biological material in the Directive, specifically in Article 9, stand in the way for the national patent legislation[1] to (additionally) allow absolute protection for the product (the DNA) as such, whether or not the DNA expresses its function and must the protection provided by Article 9 therefore be considered exhaustive?

"3. Does it make any difference to the answer to the previous question that the patent was applied for and granted (on 19 June 1996) prior to the Directive being adopted? Can you, on answering the previous questions, take into consideration the TRIPS Treaty, specifically the Articles 27 and 30?"

[1]"In Article 53 ROW95, in so far as relevant this article provides: A patent gives the patent holder (…) the exclusive right: a. to manufacture the patented product in or for his business, to use, bring into circulation or further sell, to rent out, to supply or otherwise trade, or to this end offer , import or have in stock."

IN THE NAME OF THE QUEEN

DECISION

District Court The Hague

Sector Civil Law

Decision dated 19 March 2008

In the case number/docket number 249983/ HA ZA 05-2885 in respect of:

the legal entity incorporated under foreign law
MONSANTO TECHNOLOGY LLC,
registered in St. Louis, Missouri, United States of America,
claimant,
Attorney of Record Mr. H. J. A. Knijff,
Lawyers Mr. W. A. Hoyng and Mr. F. W. E. Eijsvogels of Amsterdam,

versus

the private company with limited liability
1. CEFETRA B.V.,
2. CEFETRA FEED SERVICE B.V.,
3. CEFETRA FUTURES B.V.,
all registered in ROTTERDAM,
defendants,
Attorney of Record Mr. P. J. M. Schmidt auf Altenstadt,
Lawyer Mr. J. J. Allen of Amsterdam,

and versus

1. the corporate body governed by public law
the STATE **OF ARGENTINA,**
seated in Buenos Aires, Argentina,
and **MIGUEL SANTIAGO CAMPOS,**
acting in The capacity of Secretary of State for Agriculture, Animal Husbandry, Fisheries and Food on behalf of the State of Argentina,
joinder party with Cefetra B. V., Cefetra Feed Service B. V. and Cefetra Futures B.V.,
Attorney of Record Mr. E. D. Drok,
Lawyers Mr. M. R. Gerritsen and Mr. A. J. Verbeek of Amsterdam,

and in the case number/docket number 270268 / Ha ZA 06-2576 of:

the legal entity incorporated under foreign law
MONSANTO TECHNOLOGY LLC,
registered in St Louis, Missouri, United States of America,
claimant,
Attorney of Record Mr. H. J. A. Knijff,
Lawyers Mr. W. A. Hoyng and Mr. F. W. E. Eijsvogels of Amsterdam

versus

1. the private company with limited liability
VOPAK AGENCIES ROTTERDAM B. V.,
registered in Rotterdam,
defendant
non appearance,

2. the legal entity incorporated under foreign law
ALFRED C TOEPEER INTERNATIONAL GMBH,
registered in Hamburg, Germany,
defendant,
Attorney of Record Mr. P. J. M. Schmidt auf Altenstadt,
Lawyer Mr. J. J. Allen of Amsterdam.

Parties will hereinafter be referred to as Monsanto, Cefetra (Cefetra B. V., Cefetra Feed Services B.V. and Cefetra Futures B.V. collectively), Argentina, Vopak and ACTI.

1. The course of the proceedings

1.1. The course of the proceedings with docket number 05/2885 can be established from:
- the summons dated 14 July 2005 and the exhibits entered by Monsanto 1 to 14 inclusive;
- the interim statement for joinder by Argentina;
- the interim statements of defence by Monsanto and Cefetra;
- the decision in the interim proceedings dated 29March 2006 whereby Argentina is allowed to join the proceedings together with Cefetra;
- the statement of defence by Cefetra with two exhibits;
- the statement of defence by Argentina;
- the statement of reply with exhibits 15 to 27 inclusive;
- the statement of rejoinder by Cefetra with exhibit 3;
- the statement of rejoinder by Argentina with 13 exhibits;
- the exhibits (not numbered sequentially) 1 to 12 inclusive entered by Monsanto during the arguments presented on 26 October 2007, the exhibits 4 and 5 entered by Cefetra and the exhibit 1 entered by Argentina;
- the written summaries of the arguments by Monsanto and Cefetra and the written statement by Argentina.

1.2 The course of the proceedings with docket number 06-2576 can be established from:
- the summons dated 18 April 2006 and the exhibits entered by Monsanto 1 to 11 inclusive;
- the statement of defence by ACTI with two exhibits;
- the statement of reply, together with exhibit containing a request for reduction of claim with 15 exhibits;
- the statement of rejoinder by ACTI with exhibits 3 and 4;
- the exhibits (not numbered sequentially) 1 to 12 inclusive entered by Monsanto during the arguments presented on 26 October 2007, and the exhibits 5 and 6 entered by ACTI;
- the written summaries of arguments by Monsanto and ACTI.

1.3 Leave to proceed in default of appearance was granted to Vopak in the proceedings having docket number 06-2576.

1.4 Judgment has been further scheduled today.

2. The facts

The following facts will be taken as the basis in these proceedings.

2.1 Monsanto is engaged in research, development and trading in agricultural products.

2.2 Argentina is an important producer of soy beans. Soy beans are used as a basic material in the food industry. Soy oil is obtained by pressing the beans. The residual material is processed into soy pellets and soy meal and sold for animal feed. This “crushing” process involves the following steps.

2.2.1 The harvested soy beans are first dried, hardened, crushed and the husks removed.

2.2.2 The crushed beans are then softened using a steam treatment and fed through presses which results in soy “flakes”

2.2.3 The oil is then extracted from these oil-rich flakes in reactors using a special solvent such as hexane.

2.2.4 To remove the solvent from the flakes, these flakes are once again treated using heat and steam.

2.2.5 The dried flakes which have now been obtained after these processes are either ground to soy meal or steam pressed into compact pellets.

2.3 Monsanto is the holder of the European patent granted to Monsanto on 19 June 1996 under number EP 0 546 090 relating to "Glyphosphate tolerant 5- enolpyruvylshikimate-3 phosphate synthesis") (hereinafter referred to as: the patent). The patent is valid in Austria, Belgium, Switzerland, Germany, France, United Kingdom, Italy, Lichtenstein, Luxemburg, the Netherlands and Sweden. Following opposition, the final amended claims are as follows.

1. An isolated DNA sequence encoding a Class II EPSPS enzyme, said enzyme being an EPSPS enzyme having a K_m (PEP) between 1 – 150 µM and a K_i (glyphosate)K_m (PEP) ratio between 3-500, which enzyme is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.

2. A DNA sequence of Claim 1 wherein said K_m for phosphoenolpyruvate is between 2-25 µM.

3. A DNA sequence of Claim 1 wherein said K_i/K_m ratio of between 6-250.

4. An isolated DNA sequence encoding a protein which exhibits EPSPS activity wherein said protein is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO: 5.

5. The DNA sequence of Claim 4 wherein said antibodies are raised against a Class II EPSPS enzyme of SEQ ID NO:3.

6. A DNA sequence encoding a Class II EPSPS enzyme selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

7. A recombinant, double-stranded DNA molecule comprising in sequence:

a) a promoter which functions in plant cells to cause the production of an RNA sequence;
b) a structural DNA sequence that causes the protection of an RNA sequence which encodes a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes SEQ ID NO:3 and SEQ ID NO: 5 and
c) a 3’ non-translated region which functions in plant cells to cause the addition of a stretch of polyadenyle nucleotides to the 3’ end of the RNA sequence

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with the said DNA molecule.

8. The DNA molecule of Claim 7 in which said structural DNA sequence encodes a fusion polypeptide comprising an amino-terminal chloroplast transit peptide and a Class II EPSPS enzyme.

9. The DNA molecule of Claim 8 wherein said structural DNA sequence encoding a Class II EPSPS enzyme is selected from the group consisting of SEQ ID NO:2, SEQ ID NO: 4 and SEQ ID NO: 6.

10. The DNA molecule of Claim 9 wherein said sequence is from SEQ ID NO:2.

11. A DNA molecule of Claim 8 in which the promoter is a plant DNA virus promoter.

12. A DNA molecule of Claim II in which the promoter is selected from the group consisting of CaMV35S and FMV35S promoters.

13. A DNA molecule of Claim 7 in which said structural DNA encodes a Class II EPSPS enzyme selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO:5.

14. A method of producing genetically transformed plants which are tolerant toward glyphosate herbicide, comprising the steps of

a) inserting into the genome of the plant cell a recombinant, double-stranded DNA molecule comprising:

i) a promoter which functions in plant cells to cause the production of an RNA sequence,
ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a 5 fusion polypeptide comprising an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5,
iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene;

b) obtaining a transformed plant cell; and
c) regenerating from the transformed plant cell a genetically transformed plant which has increased tolerance to glyphosate herbicide.

15. The method of claim 14 wherein said structural DNA sequence encoding a Class II EPSPS enzyme is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO:4 and SEQ ID NO: 6.

16. The DNA module of Claim 15 wherein said sequence is that as set forth in SEQ ID:2.

17. A method of Claim 14 in which the promoter is from a plant DNA virus.

18. A method of Claim 17 in which the promoter is selected from the group consisting of CaMV35S and FMV35S promoters.

19. A method of Claim 14 in which said structural DNA encodes a Class II EPSPS enzyme selected from the group consisting of SEQ ID No:3 and SEQ ID NO:5.

20. A glyphosate tolerant plant cell comprising a DNA molecule of Claims 8, 9, 12 or 13.

21. A glyphosate tolerant plant cell of Claim 20 in which the promoter is a plant DNA virus promoter.

22. A glyphosate tolerant plant cell of Claim 21 in which the promoter is selected from the group consisting of CaMV35S and FMV35S promoters.

23. A glyphosate tolerant plant cell of Claim 20 selected from the group consisting of corn, wheat, rice, soybean, cotton, sugar beet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, apple and grape.

24. A glyphosate tolerant plant comprising plant cells of Claim 20.

25. A glyphosate tolerant plant of Claim 24 in which the promoter is from DNA plant virus promoter.

26. A glyphosate tolerant plant of Claim 25 in which the promoter is selected from the group consisting of CaMV35S and

27. A glysophate tolerant plant of Claim 26 selected from the group consisting of corn, wheat, rice, soybean, cotton, sugar beet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, apple and grape.

28. A method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of:

a) planting said crop seeds or plants which are glyphosate tolerant as a result of a recombinant double-strand DNA molecule being inserted into said crop seed or plant, said DNA molecule having:

a promoter which functions in plant cells to cause the production of an RNA sequence,
ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a polypeptide which comprises an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5,
iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene: and

b) applying to said crop and weeds in said field a sufficient amount of glyphosate herbicide to control said weeds without significantly affecting said crop.

29. The method of Claim 28 wherein said structural DNA sequence encoding a Class II EPSPS enzyme is selected from the sequence as set forth in SEQ ID NO:2.SEQ ID NO:4 or SEQ ID No:6.

30. A method of Claim 29 in which the said DNA molecule contains a structural DNA sequence from SEQ ID NO:2.

31. A method of Claim 30 in which said DNA molecule further comprises a promoter selected from the group consisting of CaMV35S and FMV35S promoters.

32. A method of Claim 31 in which the crop is selected from the group consisting of corn, wheat, race, soybean, cotton, sugar beet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, apple and grape.

33. The method of Claim 28 wherein said structural DNA sequence encodes a Class II EPSPS enzyme selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5.

2.4 The herbicide glyphosate is used when cultivating soy beans on a large scale. The glyphosate works by inhibiting the enzyme 5-enol-pyruvylshikimaat -3 phosphate synthesis, (also called EPSPS) which is present in the plant. This enzyme is important for the production of aromatic amino acids, these being necessary for the plant growth. The patent describes a class of EPSPS enzymes which are not sensitive to glyphosate, the so-called Class II enzymes. Glyphosate blocks the active centre of Class I EPSPS enzymes whereby the production of aromatic amino acids is disturbed. The plant cannot produce any or at least cannot produce sufficient proteins without these aromatic amino acids and therefore dies off. Plants possessing Class II EPSPS enzymes do not have this problem so they survive the use of glyphosate whilst the weeds around them die. The genes encoding these enzymes have, according to the description, been isolated from three different bacteria. This gene is inserted into the plant DNA whereupon the plant makes a glyphosate resistant EPSPS enzyme and the plant becomes glyphosate tolerant. Monsanto has applied this technique in its RR (Roundup Ready) soy bean. The RR soy bean plant makes the Class II EPSPS enzyme CP4-EPSPS.

2.5 The RR soy bean is cultivated on a large scale in Argentina. There is no patent protection for the Monsanto invention in Argentina.

2.6 Cefetra and ACTI trade in soy meal.

2.7. The vessel KEOYANG NOBLE arrived in Amsterdam harbour on 16 June 2005 with a cargo of soy meal from Argentina intended for Cefetra Futures B.V. The cargo was detained by Customs on the grounds of the Anti-Piracy Regulation (Regulation (European Union) number 1383/2003, further: APR). The cargo was released once Monsanto had taken samples.

2.8. On 21 March 2006, the vessel CATALINA arrived in the Netherlands with another cargo of soy meal from Argentina. The YASA PIONEER also arrived with such a cargo on 11 May 2006. These cargoes were also detained by the Customs and released once again after Monsanto had taken samples. The CATALINA cargo was reported to the Customs by Vopak.

2.9. Monsanto took the sample to determine whether the soy meal originated from RR soy beans (thus soy beans which have come from soy plants under the patented technique).

3. The Claims

3.1. Monsanto bases its claims on the previously stated facts and on the following statements.

3.1.1. An extensive test (test 1) showed the presence of CP4 –EPSPS in the soy meal. Test 2 showed the presence of the DNA sequence which encodes for CP4-EPSPS. According to Monsanto, the imported soy meal complies with the product claims 1 – 8 and 11 – 13 and is then moreover, according to Monsanto, is to be regarded as a directly obtained product by application of the protected method as per claims 14,17 – 19 and 28.

3.1.2. The cargoes in the CATALINA and YASA PIONEER were intended for ACTI.

3.1.3. Cefetra B. V., Cefetra Feed Service B.V. and Cefetra Futures B. V. should be identified as one.

3.1.4. The defendants breached or at least threatened to breach the patent rights held by Monsanto by importing soy meal into the European Community. With the exception of Vopak, they do this intentionally. Besides this, the import is illegal as this is contrary to the prohibition in Article 16 APR. The defendants also acted unlawfully against Monsanto in the Netherlands and in other countries where the patent is applicable by inciting breach of the patent, supporting and profiting from this.

3.2. Following the reduction in claim (in the case against Cefetra the claim was reduced when the arguments were submitted) Monsanto claims, stated in brief:

3.2.1. a prohibition based on Article 16 APR;

3.2.2. an injunction prohibiting infringement of the patent in all countries where the patent is applicable;

3.2.3. order the defendants (with the exception of Vopak) to pay damages in accordance with a damage statement to be drawn up in accordance with the law or – according to the choice to be made by Monsanto – payment of the profits received and also to order the defendants to provide accounts for the said profits;

3.2.4. various aspects on penalty of fines and for the defendants to pay the costs of the proceedings.

3.3. Vopak did not submit any defence against the claims. The other defendants disputed the claims.

4. The Decision

4.1. This Court has jurisdiction to give a decision on the claims as the defendants have not contested this jurisdiction and the validity of the stated patent is not in dispute in these proceedings.

4.2 Cefetra B. V., Cefetra Feed Service B.V. and Cefetra Futures B.V. do not dispute that they, as stated by Monsanto, are together responsible for importing the cargo brought by the KEOYANG NOBLE, so that the Court will proceed from this position.

4.3. ACTI has pointed out that Monsanto took samples from holds 1 and 2 on board the CATALINA, this cargo however was not intended for ACTI but for the company Agrenco. Monsanto then stated that hold 7 was indeed intended for ACTI. However, no samples were taken from the cargo in that hold. In these proceedings therefore, it cannot be assumed that ACTI, by importing the cargo of the CATALINA, committed a breach of patent. However, ACTI does not dispute that the YASA PIONEER cargo which was tested by Monsanto was intended for ACTI so it has to be investigated whether ACTI, by importing this cargo, committed a breach of patent.

4.4. Claims 1 and 4 and the interdependent claims 2 and 3 respectively 5 all claim protection for an isolated DNA sequence. Cefetra and ACTI have rightfully taken the position that there can be no question of breach of these claims as the DNA is not present as isolated matter but is incorporated in the soy meal. The Court cannot follow Monsanto in its reasoning that the DNA sequence has been taken out of its natural environment – the bacterial chromosome- and has been encoded in the DNA of the soy plant and, for this reason, the bean meal should be regarded as an isolated DNA sequence, or, that it contains this. The average person skilled in the art would understand the term isolated DNA as DNA that has been retrieved from the cell (core) of an organism for further treatment in a manner as is usual in the relevant profession. Monsanto has not put forward any reasons to assume that the average person skilled in the art would interpret this term within the context of the patent in any other manner than the usual understanding of the term.

4.5 The interpretation that the soy meal can be regarded as a directly obtained product by application of the claimed methods as per claims 14, 17-19 and 28 is also rejected. It can be accepted that the soy plant and soy bean have been directly obtained by the method. By means of the previously described crushing process, the beans are then separated, in a number of treatment stages, and worked into different components with a new identity. This process is too drastic to still assume a direct relationship between the method and the soy meal.

4.6. In view of the above, investigation of the stated breach in respect of claims 6, 7, 8, 11, 12 and 13 remains. These product claims all relate to a DNA sequence or a DNA molecule.[1]

4.7. Monsanto states that the DNA sequence intended in claim 6 – in brief, the sequence which encodes for the synthesis of a Class II EPSPS enzyme- was found in the samples taken from the cargo of the KEOYANG NOBLE. In corroboration of its statement, Monsanto also submitted exhibit 8b with the summons, being the test reports from Eurofins Analytik GmbH, this being - which has not been contradicted - an independent laboratory in Hamburg.

4.8. Cefetra and Argentina have, in summary, together argued against these reports that the DNA sequence is only present in the soy meal in fragmented form. This fragmentation is, according to them, caused by heating during the crushing process. By reason of the analysis technique applied by Monsanto, this being PCR, these fragments are said to have "stuck together" so leading to incorrect test results. Cefetra and Argentina further state that, in so far as the DNA sequence is present in intact form – this would only concern a minimal amount. They consider the calculation method followed in exhibit 21 to be incorrect. Cefetra and Argentina point out that the tests were carried out by Monsanto themselves and moreover, that it has not been determined that the tests carried out were on the cargo samples from the KEOYANG NOBLE as no "chain of custody" has been stated.

4.9. Occasioned by the criticism put forward by Cefetra and Argentina in respect of the analyses carried out, Monsanto had new tests done to show that the analysis results had not been influenced by the "sticking effect" (by Monsanto referred to as "Splicing by overlap extension of SOE") of the applied PCR technique. Monsanto submitted the analysis report of the "Gel-slice-test" carried out by Monsanto as exhibit 11 in the argumentation with as conclusion that intact DNA was present and that the executed test method excluded the possibility of DNA fragments "sticking together". Cefetra and Argentina have not stated that (also) these further tests were incorrectly executed or that they doubted the tests for any other reason. They have not supported their objections submitted under 4.8 by means of own analyses or in any other manner. Argentina solely refers to exhibit 1 in the rejoinder in which a summary is given of the conclusions of an expert investigation which was carried out without the report itself by the expert being entered. The source of this summary is not stated.

4.10 According to Cefetra and Argentina, the report submitted by Monsanto as exhibit 21 incorrectly assumes that the DNA is just as fragile at each point. According to Cefetra and Argentina DNA contains sections which are extremely sensitive to fracture ("hot spots"). However, this statement is also not supported in any way.

4.11. As appendix to the exhibit 8b with the summons, Monsanto submitted the exhibits relating to the shipping of the tested samples. A section of the exhibits apparently originate from SGS Nederland B.V. and state that the samples concerned were taken from the cargo of the KEOYANG NOBLE on 15 June 2006.

4.12. Monsanto has adequately shown by these submitted exhibits that the specified DNA sequence in claim 6 was present in considerable quantity in the KEOYANG NOBLE cargo. It is true that Cefetra and Argentina correctly argue that a section of the analyses were carried out by Monsanto itself but now that, in respect of the results, they do not state any support for their objections and also have not offered to prove the correctness of their statements by means of an expert report or by any other means, the Court does not see any reason to doubt the correctness of the results or the exhibits entered in the proceedings by Monsanto or the origin of the samples. In addition, the further tests as submitted were not contested so the correctness of these can be taken as premise.

4.13. Even should it have to be assumed that the DNA sequence is only present in the soy meal in minimal quantity, this does not deter from the fact that there is a breach of the Monsanto patent, if and to the extent that the scope of protection extends to the product, the DNA, as such (this question being dealt with hereinafter). In this situation, there is no reason to refuse Monsanto its patent rights, all the more as the DNA is present in the soy meal as a consequence of using the advantages provided by the patent. Possibly it would have to be judged that Monsanto can no longer appeal to its patent rights in opposition

[1] The Court would note that in the United Kingdom, where it was initially judged that there was no question of breach of patent on 10 October 2007, claim 6 has apparently been adapted and thus also refers to isolated DNA

to the trading in soy meal should the DNA present have to be regarded as a coincidental contamination, for example from a previous cargo. That this situation arises here however has not been stated nor has such otherwise been established.

4.14. Also ACTI has stated that, at most, only small remaining quantities of the intact DNA sequence can be found in the soy meal. On the same grounds as stated previously, Monsanto, also in respect of the cargo on the YASA PIONEER, has shown sufficiently by the submitted analyses reports (specifically exhibits 20 and 22a in the statement of reply and in the report submitted as exhibit 10 in the arguments) that the DNA sequence specified in claim 6 was present in considerable quantities in the cargo.

4.15. Proceeding from the presence of the DNA sequence specified in claim 6 in the soy meal, it is now the question as to whether, for all these reasons, there has been a breach of the Monsanto patent rights by trading the meal in the European Community. Cefetra, Argentina and ACTI consider this is not the case. In connection with this aspect, they state the following.

4.15.1. The scope of the protection for the claimed DNA sequence in claim 6 (and the claimed DNA molecule in claims 7, 8, 11, 12, and 13) is solely determined by Article 53a National Patent Act 1995 (hereinafter referred to as ROW95) specifically paragraph 3 of this Article. Article 53a is incorporated in the ROW 95 in implementation of the European Parliament and Council Directive 98/44/EG dated 6 July 1998 relating to the protection of biotechnological inventions (hereinafter referred to as: the Directive), more specifically Articles 8 and 9, which Articles provide as follows:

> Article 8:
>
> 1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
>
> 2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
>
> Article 9
>
> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

In accordance with these Directive Articles, Article 53a ROW95 provides:

> 1. In respect of a patent for biological material possessing specific characteristics as a result of the invention, the exclusive right extends to each biological material obtained by means of propagation or replication in the same or divergent form and which posses the same characteristics.
>
> 2. In respect of a patent for a method for the production of biological material possessing specific characteristics as a result of the invention, the exclusive right extends to the biological material which has been directly obtained by this method and to each biological material is obtained by propagation or replication in the same or divergent form from the directly obtained biological material and which posses the same properties.
>
> 3. In respect of a patent for a product which consists of genetic information or which contains such genetic information, the exclusive right extends to each material in which

this product is incorporated and in which the genetic information is incorporated and expresses its function, without prejudice to Article 3, first paragraph, sub-section b.

4.15.2. From the Directive and the legislative history of the implementation law, it follows that Article 53a ROW95 is intended to exclusively govern the scope of protection. It can therefore be noted as lex specialis in respect of the general protection offered by Article 53 ROW95 for a patented product. As the DNA present in the soy meal can no longer express its function – soy meal is dead material- Monsanto cannot object to trading in soy meal solely on the grounds that the DNA is present in the soy meal, thus still according to Cefetra, Argentina and ACTI.

4.16. The arguments for the standpoint taken up by Cefetra, Argentina and ACTI can be summarized as follows.

4.16.1. There is a relationship between patentability and the scope of protection. The limited patentability (and thus also scope of protection) is clarified in the preamble to the Directive under 23 and 24 in which these considerations are as follows:

> (23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;
>
> (24) Whereas, 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;

4.16.2. In a letter addressed to the Argentinean Ambassador dated 9 August 2006, the European Commission endorsed the standpoint as set out. The letter states (in the English translation):

> Therefore, according to Article 9 of the Directive, it is not enough that the genetic information has been incorporated in the product and that it is always present in the same, but that it is also necessary that this genetic information bears its function (….) Consequently, the protection to the patents cannot be extended to the derived products in which the genetic information is residual and does not exercise its genetic function.

4.16.3. The Explanatory Memorandum accompanying the draft for the implementation legislation takes up the same standpoint. The Explanatory Memorandum (Second Chamber, consultation year 1998 -1999, 26568 (R1638) Number 3, Page 16) states concerning the relationship between Article 53 ROW95 and the proposed Article 53a ROW95:

> (…) The proposed Articles (…) 53a ROW95 do not add anything to these exclusive allowable actions (stated in Article 53 ROW95 – addition by Court) but explicitly state how this product, in the case of a biotechnological invention to which the sole right is applicable, should be understood. It is indeed so that the characteristic of biotechnology is that its subject is live material, that is to say that the biological material can reproduce or can be replicated in a biological system. The product therefore should not only be seen as that which has been directly obtained by application of the invention but also as that which has been obtained by propagation, namely reproduction and replication and has the same properties (…) The three subsections refer to three different situations. The first paragraph refers to the patented biological material which is replicated, the second paragraph refers to a patented method by which biological material is obtained that is then replicated and the third paragraph refers to a product comprising genetic material or containing such information.
>
> It is stated in the first and second paragraphs that the biological material obtained by propagation or replication does not have to be obtained in the same form but must have the same properties. There has to be a question of durability of the properties encoded by the invention and these properties must also be actually present. If the properties obtained by the invention do not pass on to the progeny of the plant, the patent protection does not extent to the plant's progeny.
> In essence, the same is determined in the third paragraph, although these conditions are adapted to the fact that this concerns genetic information. Therefore, it is laid down that the

> genetic information does not only have to be encoded in the material but also has to exercise its function. In other words, if due to certain genetic modification, a certain altered gene is present in all the cells of a plant or animal but for one reason or another the altered gene does not function as intended, then the patent protection does not extend to that plant or animal.

4.16.4. Cefetra, Argentina and ACTI have submitted a decision by the Spanish judge (Juzgado de lo mercantile no 6) dated 27 July 2007 in the case of Monsanto- Sesostris S.A.E. In this case, which also involves EP 0 546 090, the Spanish judge ruled that the soy meal, in which the patented DNA sequence is present, does not fall under the protection of the patent as the DNA in the meal no longer expresses its function.

4.16.5. Cefetra, Argentina and ACTI have furthermore also submitted an opinion on the same lines by Professor Dr. Dres. h.c. Joseph Strauss, attached to the Max Planck Institute for Intellectual Property in Munich, who, according to his statement, played an important role in the realization of the Directive.

4.16.6. Lastly, a decision by the English High Court of Justice dated 10 October 2007 was submitted in respect of the case Monsanto – Cargill in which – proceedings from the amended claims and partly on other grounds than are relevant at present – it was ruled that the import of soy meal made from RR beans, does not infringe the Monsanto patent. (This last decision seems to be of less importance in so far as the Directive does not play any part. The Court will, partly due to the fact that there is apparently an on-going appeal against the Court decision and that this decision was given in proceedings between other parties, stay the decision in respect of the breach of patent in the United Kingdom as stated hereinafter under 4.31.)

4.17. Monsanto submits the following in reply.

4.17.1. Soya meal is not a biological material within the context of the Directive. Article 8 of the Directive and the implementation thereof in the Articles 53a, paragraphs 1 and 2 ROW95 are therefore not relevant for determination of the scope of protection. This also applies to Article 9 of the Directive / Article 53a, paragraph 3 ROW95 as soy meal is also not material within the context of these articles.

4.17.2. The scope of protection therefore also has to be judged on the basis of Article 53, paragraph 1 sub a ROW95. This condition gives full protection to the product, the patented DNA sequence. There is no reason to assume that the Dutch legislator wished to limit this scope of protection or that the Directive dictates this. On the contrary, the Directive intends to extend the scope of protection for biotechnological inventions.

4.17.3. Should the stated provisions of the Biotechnology Directive indeed be applicable, Monsanto submits that it can rely on Article 8, paragraph 1 of the Directive / 53a paragraph 1 ROW95 as the DNA found in the cargo concerns biological material obtained by means or propagation or replication and has the same properties. In that case, Monsanto also relies on Article 9 Directive/ 53a paragraph 3 ROW95 as the DNA sequence, the product, is incorporated in the soy meal and expresses its function. According to Monsanto, the requirement that the DNA expresses its function means that it is sufficient that the DNA has exercised its function (namely the provision of resistance to glyphosate in the soy plant) or that the DNA, should it be isolated from the soy meal, can be incorporated in a cell in a soy plant and can then (once again) exercise its function.

4.18. In support of its position that the Directive does not detract from absolute product protection provided by Article 53 ROW95 in addition to the protection provided by the Directive in Articles 8 and 9, Monsanto put forward the following arguments.

4.18.1. It cannot be derived from the Directive that it is the intention to limit the protection of biotechnological inventions in the Member States. Such a limitation, according to Monsanto, is not compatible with Article 27 of the TRIPS- Treaty (Agreement in respect of trading aspects in intellectual property, Trb.1995, 130). Monsanto reads this purpose to extend the scope of protection into Articles 8 and 9 of the Directive and also in the preamble sub 46. The preamble there provides:

> (46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the

use of patented, non-self-reproducing products, that is to say the production of the patented product itself;

4.18.2. Monsanto quotes from the report of the European Commission to the Council and the European Parliament dated 14 July 2005 dealing with "Development and implications of patent law in the field of biotechnology and genetic engineering" (COM (2005)312 final):

> On examination of the detailed provisions of the Directive, it can be seen that Articles 8, 9, 10 and 11 make up Chapter 2 of the Directive which is entitled "Scope of Protection". However none of these articles addresses the concept of a restricted scope of protection relating to the specific use identified for the gene sequence concerned. Indeed, Articles 8 and 9 establish that the protection conferred by a patent extends to any biological material obtained from the claimed product or in which the claimed product in incorporated and the same genetic information expresses its function. This might be seen as arguing for a broader scope of protection rather than a restricted one, subject of course to the exclusion under Article 5(1) of claims to the human body in its entirety.
>
> (….)
>
> The informal Group of Experts met in March 2003 to discuss this issue. A majority of the Group felt there were no objective reasons to create a specific regime of purpose-bound protection in this area differing from the classic patent protection. In particular, legal and technical experts felt there were no differences between DNA sequences and chemical substances which would justify different treatment as regards the scope of the patent protection.

4.18.3. Monsanto considers supported in its statement by the opinions of the German judge (in a ruling published in GRUR 2003, 905) and in the German literature (Keukenschrijver) and moreover in the article by Kupecz in BIE2006/3. The latter asks whether an "purpose bound " protection of the DNA sequence as, according to the writer, introduced in Germany and France, are permitted under the Directive.

4.19. On assessing that stated above, the Court first determines that for the applicability of the provisions contained in the Directive not the allegedly infringing material is relevant, the soy meal and the DNA present therein, but that the patent was granted for biological material as meant in Article 2 Directive / Article 1 ROW95. This is without doubt the case here so that, in principle, the Article 8 and 9 of the Directive/ Article 53a ROW95 are applicable.

4.20. Section 3 of Article 53a ROW95 places, in accordance with Article 9 Directive, each material in which DNA is incorporated within the scope of the exclusive right of the patent holder, should the genetic information be incorporated in that material and express its function therein. There is a question of this in this situation in so far as the soy meal is the result of the crushing process and the DNA is present in this meal. The DNA can however, naturally not express its function in dead material. The opinion of Monsanto, that it is sufficient that the DNA has expressed its function in the soy plant at a given moment or could be able to express its function once again after having been isolated from the soy meal and incorporated in live material, is not compatible with the wording of the provision and moreover, nothing indicates that the Community legislature intended such a wide scope. On the other hand, it must be considered that a gene, also as part of an organism does not continually need to express its function. There are genes which are only activated in certain stress situations such as heat, dry conditions or disease. Moreover, the Court considers it not to be without importance that, on growing the soy plants from which the meal has been made, the invention has been profited from without there being any reimbursement. Partly in view of the questions stated hereinafter to the European Court of Justice, for which reply is necessary for the decision of the dispute, the Court sees occasion, also on this point, to refer the questions as outlined under 4.30 to the European Court of Justice.

4.21. Article 53a paragraph 1 ROW95 has no independent meaning for the determination of the scope of protection for the Monsanto patent as, after replication, the replicated DNA itself complies with the description in the presented claims and thus, just as the original DNA, directly comes into

consideration for protection. Also for this replicated DNA however, the question arises if, after processing in a different material, the scope of protection is limited to the situation that the DNA expresses its function.

4.22. Should it not be possible to prohibit the trading of soy meal on the grounds of Article 53a paragraph 3 ROW95, the question becomes relevant as to whether the classic absolute protection of the product in Article 53 ROW95 in a case such as the present, continues to exist beside the specific protection provided by Article 53a paragraph 3.

4.23. An argument can be derived for an affirmative answer from the legislative system. In Article 53c paragraph 1 ROW95, an exception is expressly formulated (the farmers' privilege) in respect of the protection given in principle by Articles 53 and 53a ROW95. On the contrary, Article 53a does not state that it forms a deviation from Article 53, which would be expected should Article 53a be applicable to the situations as described therein, with the exclusion of Article 53.

4.24. It cannot be deduced from the Explanatory Memorandum with the draft for the implementation law referred to by Cefetra/ Argentina and ACTI that the statement presented by Monsanto is incorrect. It is stated that Article 53a does not extend the extent of protection, not that Article 53a limits this protection. The Explanatory Memorandum in Reply to the First Chamber (First Chamber, consultation year 2003-2004,26568 (R 1638), B, page 11) states the following.

> An animal which eats a GM crop in which a resistant gene is incorporated, can only become resistant should the resistant gene also produce a protein whereby the animal becomes resistant. Normally speaking, this is not the case and the DNA of the resistant gene from the GM crop will be broken down in the stomach/intestines of the animal and thus be ended without having any influence on the animal's immunity. The crop in which a patented resistant gene is incorporated will thus be broken down fairly quickly after consumption and then no longer be present as such in the animal. Only as long as the patented resistant gene is to be found in the animal and therein also expresses its function will there be a question of patent protection as intended in Article 9 of the Directive. As stated, the period will be extremely short, all the more as immunization in this manner does not lead to changes in the genome of the animal involved.

This passage comes close to the case under discussion but the text seems to be limited to an explanation of Article 9 of the Directive and not so much to the relationship with the classic product protection.

4.25. It cannot be deduced from the foregoing that the legislature has taken up a clear standpoint concerning the relationship between 53a ROW95 and 53ROW95. The ROW95 however serves to be interpreted so far as possible in accordance with the intentions of the Directive.

4.26. Whereas 8 of the Directive provides:

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

4.27. With due regard for this premise and now that the contrary has not been established, there seems to be reason to assume that the Directive does not detract from the absolute product protection afforded by Article 53 ROW95 but rather strives for a minimum protection. The formulation of Article 9 of the Directive seems to offer support for this opinion by using the verb "extends to" and not, for example "is limited to" or words of similar meaning. In addition, should the Directive not allow a wider protection as considered by the Spanish judge, the Court sees itself put in the awkward situation that even the isolated DNA, as long as not incorporated into any material, would not be included under the scope of

the protection. A such like limitation, as argued, does not seem to the Court to be legitimate in the light of the aim and meaning of the Directive nor in the light of protection of the public order. Moreover, this explanation seems to be difficult with Article 3, paragraph 2 and Article 5 paragraph 2 of the Directive where the patentability of the (among others) isolated DNA is confirmed. Should the Directive not detract from the absolute product protection, Article 9 of the Directive respectively 53a ROW95 paragraph 3 would offer a way out in a situation in which the DNA is no longer identifiably present, in which case Article 53 ROW95 possibly offers no further protection.

4.28. The Court considers the indications for this explanation however to be insufficiently clear. Partly in view of the considerable interests of the parties, the Court sees, as requested by Monsanto, reason to refer questions concerning the explanation of the Directive to the European Court of Justice, partly concerning the considerations as given here under 4.20.

4.29. The Court would also note that Monsanto has to a significant extent incompletely explained the meaning of the report by the European Commission dated 14 July 2005. The complete relevant part of the report is as follows:

> 2.1 Scope of patents on gene sequences,
>
> The issue to be reviewed according to the first report under Article 16c is the question of whether patents on gene sequences (DNA sequences) should be allowed according to the classical mode of the patent claim, whereby a first inventor can claim an invention which covers possible future use of that sequence, or whether the patent should be restricted so that only the specific use disclosed in the patent application can be claimed ("purpose-bound protection").
>
> On examination of the detailed provisions of the Directive, it can be seen that Articles 8, 9, 10 and 11 make up Chapter 2 of the Directive which is entitled "Scope of Protection". However, none of these articles addresses the concept of a restricted scope of protection relating to the specific use identified for the gene sequence concerned. Indeed, Articles 8 and 9 establish that the protection conferred by a patent extends to any biological material obtained from the claimed product or in which the claimed product is incorporated and the same genetic information expresses its function. This might be seen as arguing for a broad scope of protection rather than a restricted one, subject of course to the exclusion under Article 5(1) of claims to the human body in its entirety.
>
> On the other hand, it might be thought from Article 5(3) and Recitals 23 and 25 that the Community legislator had intended to at least raise the possibility of a limited scope of protection covering only the specific industrial application identified in the patent, as far as this particular type of invention is concerned. Otherwise, Article 5(3) which requires the industrial application of a gene sequence to be disclosed in the patent application, merely repeats a standard requirement of general patent law, as can be seen from Recital 22.
>
> The informal Group of Experts met in March 2003 to discuss this issue. A majority of the Group felt there were no objective reasons to create a specific regime of purpose-bound protection in this area differing from the classic patent protection. In particular, legal and technical experts felt there were no differences between DNA sequences and chemical substances which would justify different treatment as regards the scope of patent protection.
>
> Since these discussions other arguments have been brought to the table.
>
> First, there is the question of whether the fact that the human gene sequences have been isolated from the human body implies that they should be given different treatment to chemical substances on ethical grounds. This reasoning would seem to be behind the transpositions of the Directive contained in the French national law and in Germany where purpose-bound protection is provided for inventions concerning material isolated from the humans body (France) and human/primate gene sequences (Germany).

A second argument is an economic question. Is it more valuable to society to allow the first inventor a broad scope of protection so others which build on this invention should have to seek a licence, or should a patent on a gene sequence be limited in scope to allow future uses of such sequences to be patented freely? This issue has been linked to the freedom of research, although certain research exemptions already exist in patent law. More generally, it relates to the balance between investment and potential reward for the first innovator in a field compared to subsequent innovators. Economic evidence is however hard to come by and the arguments do not relate solely to the gene sequence patents as distinct from any other field of technology. The Commission has launched a study that is analyzing the extent of human DNA patenting in Europe and its potential consequences on research and innovation. The Group of Experts could be asked to consider further the impact of the research exemption.

Moreover, as a specific field of technology becomes mature, the application of the normal patent criteria of novelty, inventive step and industrial applicability means that future patents are necessarily limited in scope because the invention claimed has to be distinguished from the vast array of what is already known in the field. As it is now seventeen years since a Directive was first proposed, it may be questionable whether attempting to further refine the scope of protection of gene sequence patents in the light of the divergences between national legislations will have any significant effect on the actors in the field.

Against this background, the Commission does not at present intend to take a position on the validity of transposition according to the choice between the classical and limited scope of protection for gene sequences. The Commission will, nonetheless, continue to monitor whether there are any economic consequences of possible divergences between Member States' legislation.

4.30. This section of the report thus seems, in the first place, to deal with a limitation in the protection for DNA sequences, not so much due to the provisions determining the scope thereof in Articles 8 and 9 of the Directive but due to the requirements the patent application must comply with. Moreover, the Commission expressly does not take up a position. But whatever the implications thereof, the explanation of the Directive is reserved for the ECJ. The Court intends to refer the following questions concerning the explanation of the terms of Article 9 of the Directive before the European Court.

1. Should Article 9 of the Directive be understood such that the protection meant in this Article can also be relied upon in a situation such as in these proceedings whereby the product (the DNA) is present in a materials and does not express its function at the time of the stated breach but has indeed expressed its function or possibly, following the isolation from the material and its incorporation in the cell of an organism, could once again express its function?

2. Proceeding from the presence of the DNA sequence as described in claim 6 of the patent in soy meal imported into the European Community by Cefetra and ACTI and assuming that DNA is incorporated in the soy meal as meant in Article 9 of the Directive and that it therein no longer expresses its function:

   Does the provided protection of a patent for biological material in the Directive, specifically in Article 9, stand in the way for the national patent legislation[2] to (additionally) allow absolute protection for the product (the DNA) as such, whether or not the DNA expresses its function and must the protection provided by Article 9 therefore be considered exhaustive?

3. Does it make any difference to the answer to the previous question that the patent was applied for and granted (on 19 June 1996) prior to the Directive being adopted? Can you, on answering

[2] In Article 53 ROW95, in so far as relevant this article provides: A patent gives the patent holder (…) the exclusive right: a. to manufacture the patented product in or for his business, to use, bring into circulation or further sell, to rent out, to supply or otherwise trade, or to this end offer , import or have in stock.

the previous questions, take into consideration the TRIPS Treaty, specifically the Articles 27 and 30?

4.31. Parties will be given the opportunity to comment on these questions (Monsanto has already formulated a question in the argumentation). At a later stage in the proceedings, the parties will moreover be given the opportunity to comment on the consequences in respect of the answers to the questions for the stated breach of the patent outside the Netherlands.

4.32. Argentina has put forward the defence that the claims by Monsanto should be rejected as Monsanto is said to be abusing its rights and is said to act in contravention of the standards of reasonableness and fairness against Argentina, its agricultural sector and its European importers such as Cefetra and ACTI. The arguments put forward by Argentina, come down to, in short, that Monsanto, on the one hand has made Argentina totally dependant on its RR soy plant by stimulating the planting thereof (in the meantime more than 90% of the planning comprises the RR soy plant) whilst, on the other hand, has in no way made clear that Monsanto would oppose trading outside Argentina. According to Argentina, Monsanto was aware that an important part of the soy would be exported. Monsanto has not opposed this for many years and kept its silence. According to its statement, Argentina's interests would be extremely adversely affected should Monsanto be able to block the export to the European Community.

4.33. The Court realizes that Argentina has a considerable interest involved in the sale of soy products to the European Community. In the circumstances put forward, however, the Court does not see any grounds to accept that Monsanto is abusing its rights or is acting contrary to the requirements of reasonableness and fairness, if only on the grounds that it was predictable for Argentina that Monsanto would seek to exploit its patent rights wherever possible, that is to say not in Argentina (where the patent application by Monsanto was rejected due to a procedural reason) but in the European Community. Less important for the merits but legally decisive is moreover that Argentina has joined the proceedings to side with Cefetra and therefore only the position of Cefetra is of importance. That Monsanto abuses rights or acts contrary to the concept of reasonableness and fairness against Cefetra cannot be seen at all.

4.34. In view of that stated previously, the following is decided.

5. The decision

In the case against Cefetra, Argentina and ACTI:

The case is referred to the session of **16 April 2998 to** provide Monsanto, Cefetra/Argentina and ACTI the opportunity to present their statements in respect of the previously formulated question.

In all cases

All further decisions are stayed.

This decision is rendered by Mr. E. F. Brinkman, Mr. P. G. J. de Heij and Mr. R. C. D. E Hasekamp and pronounced in public on 19 March 2008.