United States District Court,
D. Delaware.

SYNGENTA SEEDS, INC,
Plaintiff.
v.
MONSANTO COMPANY, Dekalb Genetics Corp., Pioneer Hi-Bred International, Inc., Dow Agrosciences, LLC, and Mycogen Plant Science, Inc. and Agrigenetics, Inc., collectively d/b/a Mycogen Seeds,
Defendants.

No. Civ. 02-1331-SLR

Nov. 19, 2004.

Paul M. Lukoff, Prickett, Jones & Elliott, Wilmington, DE, for Plaintiff and Defendant.

Richard L. Horwitz, Potter Anderson & Corroon, LLP, Wilmington, DE, for Defendants and Counter-Claimants.

MEMORANDUM ORDER

ROBINSON**, J.**

At Wilmington this 19th day of November, 2004, having reviewed the papers submitted by the parties in connection with claim construction and having heard oral argument on the same;

IT IS ORDERED that the claims at issue in U.S. Patent Nos. 6,403,865 ("the '865 patent"), 6,075,185 ("the '185 patent"), and 6,320,100 ("the '100 patent") shall be construed as follows, FN1 consistent with the plain meaning of the words used in the claims (as informed by the specification and prosecution history) and the tenets of claim construction as set forth by the United States Court of Appeals for the Federal Circuit:

FN1. Plaintiff's motion for claim construction (D.I.308) is moot.

1. Claim 1 of the '865 patent**.**

1. A fertile transgenic maize plant comprising:
a foreign DNA sequence encoding a Bacillus thuringeinsis insecticidal protein toxic to European corn borer stably incorporated into the plant's genome, the foreign DNA comprising a nucleic acid coding sequence modified from the nucleic acid coding sequence of the native Bacillus thuringiensis gene encoding the insecticidal protein to increase expression of the insecticidal protein in the transgenic plant;

wherein the transgenic plant expresses the insecticidal protein in plant leaf tissue at greater than about 1-5 ng insecticidal protein per mg soluble leaf protein, and the leaf tissue causes mortality to European corn borer.

The above claim shall be construed to mean: A corn plant in which a foreign nucleic acid coding sequence, that produces a protein toxic to European corn borers and is modified from a nucleic acid coding sequence found naturally in Bacillus thuringeinsis, is introduced into the corn plant's genome such that: (1) the foreign nucleic acid coding sequence is capable of being passed along to the corn plant's progeny; and (2) the corn plant expresses greater than about 1-5 ng of the toxic protein in its leaf tissue such that the leaf tissue kills European corn borer.
Neither the plain meaning of the claim language, nor that of the specification, limit the phrase "stably incorporated into the plant's genome" to a particular target tissue (elite corn lines) or a method for ensuring stability (microprojectile bombardment). The specification indicates that the claimed invention is not limited to elite corn lines. (*See* '865 patent, col. 2, 11. 56-57; col. 14, 1. 34-col. 15, 1. 56) FN2 Similarly, the plain language of claim 1 says nothing about transformation methods; rather, claims 29 and 36 of the '865 patent are both directed to methods for producing transformed maize plants using microprojectile bombardment. By interpreting "stable incorporation" in claim 1 to require microprojectile bombardment, defendants impermissibly attempt to incorporate a process limitation into a product claim,FN3 and ignore the doctrine of claim differentiation. FN4

FN2. The portions of the prosecution history identified by defendants in support of the proposed limitation are not persuasive, as the focus of those arguments were claims directed to elite maize. (D.I. 304 at PH 2697-2703)

FN3. *See* Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed.Cir.2000).

FN4. *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1326 (Fed.Cir.2003).

2. Claim 11 of the '865 patent**.**

11. The fertile transgenic maize plant according to claim 1, wherein the foreign DNA nucleic acid coding sequence has a G + C content of at least about 60% percent.
The above claim shall be construed to mean: The corn plant of claim 1 in which the ratio of G and C nucleotides in the foreign nucleic acid coding sequence to the total number of nucleotides in the foreign nucleic acid coding sequence is 60%.
3. Claim 12 of the '865 patent**.**

12. The fertile transgenic maize plant according to claim 1, wherein the foreign DNA nucleic acid coding sequence has a G + C content of at least about 64% percent.
The above language shall be construed to mean: The corn plant of claim 1 in which the ratio of G and C nucleotides in the foreign nucleic acid coding sequence to the total number of nucleotides in the foreign nucleic acid coding sequence is 64%.
4. Claim 16 of the '865 patent**.**

16. The fertile transgenic maize plant according to claim 1, wherein the transgenic plant expresses the insecticidal protein at a level sufficient to control a field population of European corn borer below a level of

about 10 larvae/plant.
The above language shall be construed to mean: The corn plant of claim 1 which will express the insecticidal protein at levels sufficient to keep the field population of European corn borer below 10 neonate larvae per plant.
5. Claim 18 of the '865 patent**.**

18. The fertile transgenic maize plant according to claim 1, wherein the foreign DNA nucleic acid coding sequence has at least about 90% homology with a nucleic acid coding sequence of an active toxin portion of a native Bacillus thuringiensis insecticidal protein, which active portion has been modified to contain 100% maize preferred codons.
The above language shall be construed to mean: The corn plant of claim 1, whereby the foreign nucleic acid coding sequence is at least about 90% identical with a nucleic acid coding sequence that encodes the active toxin portion of a native Bacillus thuringiensis insecticidal protein and has been modified to contain, at every position, the single codon that most frequently encodes each amino acid in corn.
6. Claim 19 of the '865 patent**.**

19. The fertile transgenic maize plant according to any one of claims 1-18, which is an inbred plant.
The above language shall be construed to mean: The corn plant of any one of claims 1-18 which is genetically essentially the same from generation to generation.
7. Claim 20 of the '865 patent**.**

20. The fertile transgenic maize plant according to any one of claims 1-18, which is a hybrid plant.
The above language shall be construed to mean: The corn plant of any one of claims 1-18 which is produced by crossing an elite inbred corn plant with another, genetically different inbred corn plant.
8. Claim 21 of the '865 patent**.**

21. A method of controlling infestation of maize plants by European corn borer, the method comprising: providing a transgenic maize plant according to claim 1; and contacting said European corn borer with the plant.

The above language shall be construed to mean: A method of keeping the field population of European corn borer at levels low enough to make corn plant growth economical where a corn plant of claim 1 comes into contact with European corn borers.
9. Claim 1 of the '185 patent**.**

1. A nucleic acid molecule comprising a maize-optimized nucleic acid coding sequence that encodes a CryIA(b) protein, wherein said maize-optimized nucleic acid coding sequence is produced by a method comprising:
(a) determining the amino acid sequence of said CryIA(b) protein;

(b) reverse translating said amino acid sequence into said maize-optimized nucleic acid coding sequence, wherein said maize-optimized nucleic acid coding sequence comprising a sufficient number of the single codons that most frequently encode each amino acid in maize, wherein said maize-optimized nucleic acid coding sequence has at least about 60% G+C content, and wherein the single codons that most frequently encode each amino acid in maize are determinable by

(i) pooling a plurality of gene sequences from maize,

(ii) calculating a codon usage profile from said pooled maize gene sequences, and

(iii) determining which single codon most frequently encodes each amino acid in maize; and

(c) synthesizing said maize-optimized nucleic acid coding sequence.

The above language shall be construed to mean: FN5 A nucleic acid molecule, made by human intervention, that includes a nucleic acid coding sequence that encodes a naturally occurring protein identified as a CryIA(b) protein by Hofte & Whiteley, where the native codons of the nucleic acid coding sequence have been replaced with a sufficient number of the single codons that most frequently encode each amino acid in corn so that at least about 60% of the nucleotides in the coding sequence are either G or C.
FN5. Claim 1 of the '185 patent and claim 18 of the '100 patent are considered to be "product-by-process" claims. "A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made." 3 Chisum Donald S., Chisum on Patents s. 8.05 (2003). According to binding Federal Circuit precedent, product-by-process claims are infringed where the product limitations read on the accused product, regardless of the manner in which the product was made. Scripps Clinic & Research Found., v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed.Cir.1991). Under a *Scripps* analysis, the court does not construe the language of claim 1 that describes the process by which the product is made (i.e., "determining the amino acid sequence," "reverse translating," "pooling a plurality," "calculating a codon usage profile," "determining which single codon most frequently encodes," and "synthesizing said maize-optimized nucleic acid coding sequence") except to the extent that these processes impose structural limitations on the claimed product.

The court recognizes that the Federal Circuit, in a well-reasoned subsequent case, came to a different conclusion, holding that process terms limit the product claimed. Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834 (Fed.Cir.1992). However, where Federal Circuit precedent conflicts, the earlier precedent controls. Tex. Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed.Cir.1996). As a result, the processing features of claim 1 of the '185 patent and of claim 18 of the '100 patent are not relevant to a determination of whether defendants' products infringe.
With respect to the phrase "maize optimized", the prosecution history demonstrates that the examiner had several concerns about this limitation: 1) the broad language seemed to cover nucleic acid coding sequences containing nonpreferred codons for the majority of the amino acids (D.I. 304 at PH 1425, 1587); and 2) it was unclear which codons would be considered those that are most frequently used in a plant species (*Id*. at PH 1620). To address these concerns, the examiner suggested "[a]mendment of claims to include method steps for determining maize optimized codons,FN6 and inclusion of the phrase "maize optimized nucleic acid coding sequence comprising a sufficient number/% of said single codons wherein said synthetic nucleic acid has at least about 60% GC content." (*Id*. at PH 1613) In order to address the variability in what may be regarded as the most-preferred codon, and to ensure that the most-preferred codons were sufficiently represented to satisfy a "maize optimized" limitation, the applicants amended the independent claims to recite that " 'said maize optimized nucleic acid coding sequence has at least about 60% G+C content.' Applicants note that on a general basis, according to both the Murray table and the Exhibit A table, the G+C content of the codons is directly proportional to maize's preference for them." (*Id*. at PH 1620) The examiner allowed such amended claims, stating: "The claims are deemed free of the prior art of record given that the prior art does not teach or suggest a Bt insecticidal protein gene that uses the most frequently used codon in maize to code for each amino acid such that the synthetic DNA sequence comprises at least 60% G+C content ." (*Id*. at PH 2441) The court's construction is consistent with the claim language, as informed by the specification (*see, e.g .,* '185 patent, col. 8, 11. 50-57; col. 10, 11. 65-col. 11, 11. 4) and the

prosecution history. In terms of how the G+C content is determined, the court has rejected defendants' construction, as it is inconsistent with the claim language and with the understanding of those skilled in the art. (*See* D.I. 310 at A254, 260-61, 272-73, 277-81, 288-89)

FN6. Although the applicants accepted this advice, the Federal Circuit has nullified these limitations in its *Scripps* holding.

10. Claim 2 of the '185 patent**.**

2. A nucleic acid molecule according to claim 1, wherein the single codons determined to most frequently encode each amino acid in maize are the following: Ala, GCC; Arg, CGC; Asn, AAC; Asp, GAC; Cys, TGC; Gin, CAG; Glu, GAG; Gly, GGC; His, CAC; Ile, ATC; Leu, CTG; Lys, AAG; Met, ATG; Phe, TTC; Pro, CCC; Ser, AGC; Thr, ACC; Trp, TGG; Tyr, TAC; and Val, GTG.
The above language shall be construed to mean: The nucleic acid molecule of claim 1, where the maize optimized nucleic acid coding sequence must contain a sufficient number of the listed codons so that at least 60% of the nucleotides in the coding sequence are either G or C:

Amino Acid	Codon
Alanine	GCC
Arginine	CGC
Asparagine	AAC
Aspartic acid	GAC
Cysteine	TGC
Glutamine	CAG
Glutamic acid	GAG
Glycine	GGC
Histidine	CAC
Isoleucine	ATC
Leucine	CTG
Lysine	AAG
Methionine	ATC
Phenylalanine	TTC
Proline	CCC
Serine	AGC
Threonine	ACC
Tryptophan	TGG
Tyrosine	TAC
Valine	GTG

11. Claim 4 of the '185 patent**.**

4. A nucleic acid molecule according to claim 2, further comprising a promoter capable of directing expression of a nucleotide sequence in a plant cell, wherein said promoter is operatively linked to said coding sequence.
The above language shall be construed to mean: The nucleic acid molecule of claim 2 that also includes a

regulatory nucleic acid coding sequence that is: (a) linked to the nucleic acid coding sequence optimized for corn described in claim 2; and (b) capable of promoting the reproduction of said nucleic acid coding sequence.

12. Claim 10 of the '185 patent**.**

10. A transgenic maize plant comprising the nucleic acid molecule of claim 4.

The above language shall be construed to mean: A corn plant containing genetic material from some other organism, including the genetic material that is the nucleic acid molecule of claim 4.

13. Claim 12 of the '185 patent**.**

12. A method of protecting a maize plant against European corn borer comprising:

(a) providing a transgenic maize plant according to claim 10, wherein CryIA(b) is expressed in said transgenic maize plant in an amount sufficient to control said European corn borer; and,

(b) contacting said European corn borer with said transgenic maize plant.

The above language shall be construed to mean: A method of protecting a corn plant against European corn borer, consisting of: (a) providing a corn plant of claim 10 (which produces sufficient CryIA(b) to keep the European corn borer at levels low enough that corn can be economically grown); and (b) allowing said corn plant to contact the European corn borer.

14. Claim 18 of the '100 patent**.**

18. A synthetic DNA coding sequence that encodes a Bacillus thuringiensis (Bt) insecticidal protein selected for optimized expression in a plant, wherein said synthetic DNA coding sequence is produced by a method comprising:

(a) obtaining the amino acid sequence of said Bt insecticidal protein;

(b) reverse translating said amino acid sequence into a synthetic DNA coding sequence comprising a sufficient number of the following codons: Ala, GCC; Arg, CGC; Asn, AAC; Asp, GAC; Cys, TGC; Gin, CAG; Glu, GAG; Gly, GGC; His, CAC; Ile, ATC; Leu, CTG; Lys, AAG; Met, ATG; Phe, TTC; Pro, CCC; Ser, AGC; Thr, ACC; Trp, TGG; Tyr, TAC; and Val, GTG; such that said synthetic DNA coding sequence has at least about 60% G+C content; and

(c) synthesizing said DNA coding sequence.

The above language shall be construed to mean: FN7 A nucleic acid coding sequence, made by human intervention, that encodes a Bacillus thuringiensis insecticidal protein, where the native codons in the nucleic acid coding sequence have been replaced with a sufficient number of the following codons so that at least about 60% of the nucleotides in the optimized nucleic acid coding sequence are either G or C: Ala, GCC, Arg, CGC, Asn, AAC, Asp, GAC, Cys, TGC, Gin, CAG, Glu, GAG, Gly, GGC, His, CAC, Ile, ATC, Leu, CTG, Lys, AAG, Met, ATG, Phe, TTC, Pro, CCC, Ser, AGC, Thr, ACC, Trp, TGG, Tyr, TAC, and Val, GTG.

FN7. Refer to the discussion above in footnote 4 regarding product-by-process claims.

15. Claim 21 of the '100 patent**.**

21. A chimeric gene comprising a heterologous promoter sequence operatively linked to the synthetic DNA

coding sequence of claim 18.
The above language shall be construed to mean: A gene comprised of parts that do not occur in nature that includes a regulatory nucleic acid coding sequence that is: (a) linked to the nucleic acid coding sequence of claim 18 and capable of promoting the reproduction of said nucleic acid coding sequence; and (b) has an origin different from said nucleic acid coding sequence.
16. Claim 23 of the '100 patent**.**

23. A transgenic plant cell comprising chimeric gene of claim 21.
The above language shall be construed to mean: A plant cell containing genetic material from other organisms, including the gene of claim 21.
17. Claim 24 of the '100 patent**.**

24. A transgenic plant comprising the transgenic plant cell of claim 23.
The above language shall be construed to mean: A plant containing genetic material from other organisms, including the plant cell of claim 23.
18. Claim 25 of the '100 patent**.**

25. A transgenic plant according to claim 24, which is maize.
The above language shall be construed to mean: The plant of claim 24 where the plant is corn.
19. Claim 26 of the '100 patent**.**

26. Transgenic seed from the transgenic plant according to claim 25, wherein said transgenic seed comprises the synthetic DNA coding sequence that encodes a Bacillus thuringiensis (Bt) insecticidal protein.
The above language shall be construed to mean: A seed from the plant of claim 25, where the seed includes the nucleic acid coding sequence of claim 18 which directs production of a Bacillus thuringiensis insecticidal protein.
20. Claim 27 of the '100 patent**.**

27. A method of controlling insect pests, comprising contacting the insect pests with the transgenic plant according to claim 24.
The above language shall be construed to mean: A method for keeping the field population of insect pests at levels low enough to make corn plant production economical, whereby one causes the plant of claim 24 to come into contact with insects, thereby causing harm to the insects.
21. Claim 30 of the '100 patent**.**

30. The method of claim 27, wherein said transgenic plant is maize.
The above language shall be construed to mean: The method of claim 27 where the plant is corn.
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