Appeal decision

Appeal No. 2019-2958

Appellant	Advanta Holdings B.V.
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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2017-5343, entitled "sorghum plant with increased herbicide tolerance having a mutated polynucleotide encoding a mutated acetohydroxyacid synthase large unit" (the application published on July 6, 2017, Japanese Unexamined Patent Application Publication No. 2017-118878) has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application is a divisional application filed on January 16, 2017 under the provisions of Article 44(1) of the Patent Act based on a part of Japanese Patent Application No. 2015-503768 whose international filing date is April 5, 2012. In response to the notification of reasons for rejection dated January 5, 2018, a written opinion and a written amendment were filed on July 11, 2018. The decision of final rejection was made on October 26, 2018, and, in response, an appeal against the examiner's decision of refusal was filed on March 4, 2019, and, at the same time an amendment was made. No. 2 Decision to dismiss the amendment dated March 4, 2019 [Conclusion]

The amendment dated March 4, 2019 (hereinafter, referred to as "the Amendment") is dismissed.

[Reason]

1. The Amendment

The Amendment comprises the amended matter in which Claim 11 amended by the written amendment dated July 11, 2018:

(before amendment) "[Claim 11]

An isolated sorghum grain having in the genome at least one polynucleotide encoding a polypeptide having a substitution from alanine to threonine at position 93 of sorghum AHAS protein large subunit"

is changed to Claim 10 after the amendment by the Amendment:

(after amendment) "[Claim 10]

An isolated sorghum grain having in the genome at least one polynucleotide encoding a polypeptide having a <u>single</u> substitution from alanine to threonine at position 93 of sorghum AHAS protein large subunit" (the underline indicates the matter amended by the Amendment).

2. Purpose requirements for amendment

By the above amended matter, "substitution" stated in Claim 11 before the amendment was amended to "single substitution" in Claim 10 after the amendment.

The amendment with respect to Claim 10 after the amendment restricts the invention according to Claim 11 before the amendment, and it is acknowledged that the Amendment falls under an amendment for the purpose of restriction of the scope of claims set forth in the provisions of Article 17-2(5)(ii) of the Patent Act.

In such circumstances, it is examined below whether the Appellant can be granted a patent independently for the invention specified by the matter stated in Claim 10 in the scope of the claims amended by the Amendment (hereinafter, referred to as the "Amended Invention") (whether it complies with the provisions of Article 126(7) of the Patent Act applied mutatis mutandis by Article 17-2(6) of the Patent Act).

3. Consideration on requirement for independent patentability

(1) Cited Document, and the Cited Invention

A. Cited Document 1

National Publication of International Patent Application No. 2010-523123 indicated in the examiner's decision of refusal dated October 26, 2018 (hereinafter, referred to as the "examiner's decision") as Cited Document 1 discloses the following matters. Underlines were added by the body. The same applies hereinafter. (A-1) "[Claim 1]

An isolated polynucleotide encoding an acetohydroxyacid synthase large subunit (AHAS) double mutant polypeptide selected from the group consisting of: a) a polypeptide having a valine, <u>threonine</u>, glutamine, cysteine, or methionine at a position corresponding to <u>position 122 of SEQ ID NO: 1</u> or position 90 of SEQ ID NO: 2 and a phenylalanine, <u>asparagine</u>, threonine, glycine, valine, or tryptophan at a position corresponding to <u>position 653 of SEQ ID NO: 1</u> or position 621 of SEQ ID NO: 2

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[Claim 5]

An expression vector comprising the isolated polynucleotide of Claim 1.

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[Claim 7]

A transgenic plant comprising the expression vector of Claim 5.

••••

[Claim 10]

<u>The transgenic plant</u> of Claim 7, wherein the plant is selected from the group consisting of Arabidopsis, maize, wheat, rye, oat, triticale, rice, barley, <u>morokoshi</u> (<u>sorghum</u>), millet, sugarcane, soybean, sugar beet, peanut, cotton, rapeseed, canola, Brassica species, manihot, pepper, sunflower, tagetes, solanaceous plants, potato, tobacco, eggplant, tomato, Vicia species, pea, alfalfa, coffee, cacao, tea, Salix species, oil palm, coconut, perennial grass, and a forage plant.

[Claim 11]

<u>A plant-seed produced by the transgenic plant of Claim 7, wherein the seed</u> comprises the isolated polynucleotide.

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[Claim 36]

A method of controlling weeds in the vicinity of crop plants comprising:

i) planting in a field seeds of any one of Claims 11, 18, 29, and 35; or seeds produced by the plant of any one of Claims 7-10, 14-17, 19, 25-28, and 31-34; and

ii) applying <u>an effective amount of an imidazolinone herbicide</u>, a sulfonylurea herbicide, or a mixture thereof <u>to the weeds and to the crop plants in the field to control the weeds</u>"

(scope of claims).

(A-2) "[0011]

<u>A number of single mutations in the AHAS Large subunit are known to result</u> <u>in tolerance or resistance to herbicides (</u>Duggleby et al., (2000) Journal of Biochem and Mol. Bio. 33: 1-36; Jander et al., (2003) Plant Physiology 131: 139-146). <u>For example,</u> <u>alanine to valine substitution at position 122 of Arabidopsis AHASL (or an alanine to</u> <u>threonine substitution at corresponding position 100 of Cocklebur AHASL) confers</u> <u>resistance to imidazolinone and sulfonylureas."</u>

(A-3) "[0028]

....

[Figure 3-1] is an alignment of the positions of correspondence of the Arabidopsis AHAS Large subunit protein (AtAHASL, SEQ ID NO: 1) with the AHAS Large subunit protein of a number of species where the double and triple mutations of the invention may be made showing the position of substitutions which correspond to the positions of substitution in SEQ ID NO: 1: Amaranthus sp. (AsAHASL SEQ ID NO: 9), Brassica napus (BnAHASL 1A SEQ ID NO: 3, BnAHASL 1C SEQ ID NO: 10, BnAHASL 2A SEQ ID NO: 11), Camelina microcarpa (CmAHASL 1 SEQ ID NO: 12, CmAHASL 2 SEQ ID NO: 13), Solanum tuberosum (StAHASL 1 SEQ ID NO: 16, StAHASL 2 SEQ ID NO: 17), Oryza sativa (OsAHASL SEQ ID NO: 4), Lolium multiflorum (LmAHASL SEQ ID NO: 20), Solanum ptychanthum (SpAHASL SEQ ID NO: 14), Sorghum bicolor (SbAHASL SEQ ID NO: 15), Glycinemax (GmAHASL SEQ ID NO: 18), Helianthus annuus (HaAHASL 1 SEQ ID NO: 5, HaAHASL 2 SEQ ID NO: 6, HaAHASL 3 SEQ ID NO: 7), Triticum aestivum (TaAHASL 1ASEQ ID NO: 21, TaAHASL 1B SEQ ID NO: 22, TaAHASL 1D SEQ ID NO: 23), Xanthiumsp. (XsAHASL SEQ ID NO: 19), Zea mays (ZmAHASL 1 SEQ ID NO: 8, ZmAHASL 2 SEQ ID NO: 2), Gossypium hirsutum (GhAHAS A5 SEQ ID NO: 24, GhAHAS A19 SEQ ID NO: 25), and E. coli (ilvB SEQ ID NO: 26, ilvG SEQ ID NO: 27, ilvI SEQ ID NO: 28)." (A-4) "[0051]

In particular, the present invention describes using polynucleotides encoding AHASL mutant polypeptide comprising at least two mutations to engineer plants which are herbicide tolerant. This strategy has herein been demonstrated using Arabidopsis AHASL mutants in Arabidopsis thaliana and maize AHASL 2 mutants in corn, but its application is not restricted to these genes or to these plants. In preferred embodiments, the herbicide is imidazolinone and/or sulfonylurea. In other preferred embodiments, the

herbicide tolerance is improved and/or enhanced compared to wild-type plants and known AHAS mutants.

[0052]

The invention also provides a method of producing a transgenic crop plant containing AHASL mutant coding nucleic acid comprising at least two mutations, wherein expression of the nucleic acids(s) in the plant results in herbicide tolerance as compared to wild-type plants or known AHAS mutant type plants comprising: (a) introducing into a plant cell an expression vector comprising nucleic acid encoding an AHASL mutant with at least two mutations, and (b) generating from the plant cell a transgenic plant which is herbicide tolerant. The plant cell includes, but is not limited to, a protoplast, gamete producing cell, and a cell that regenerates into a whole plant. <u>As used herein, the term "transgenic" refers to any plant, plant cell, callus, plant tissue, or plant part that contains all or part of at least one recombinant polynucleotide. In many cases, all or part of the recombinant polynucleotide is stably integrated into a chromosome or stable extra-chromosomal element, so that it is passed on to successive generations." (A-5) "[0055]</u>

The invention further provides non-transgenic and transgenic herbicide-tolerant plants comprising one polynucleotide encoding an AHASL double mutant polypeptide, or two polynucleotides encoding AHASL single mutant polypeptides. Non-transgenic plants generated therefrom can be produced by cross-pollinating a first plant with a second plant and allowing the pollen acceptor plant (can be either the first or second plant) to produce seed from this cross pollination. Seeds and progeny plants generated thereof can have the double mutations crossed onto one single allele or two alleles. The pollenacceptor plant can be either the first or second plant. The first plant comprises a first polynucleotide encoding a first AHASL single mutant polypeptide. The second plant comprises a second polynucleotide encoding a second AHASL single mutant polypeptide. The first and second AHASL single mutant polypeptides comprise a different single amino acid substitution relative to a wild-type AHASL polypeptide. Seeds or progeny plants arising therefrom which comprise one polynucleotide encoding the AHASL double mutant polypeptide or two polynucleotides encoding the two AHASL single mutant polypeptides can be selected. The selected progeny plants display an unexpectedly higher level of tolerance to an AHAS-inhibiting herbicide, such as an imidazolinone herbicide or sulfonylurea herbicide, than is predicted from the combination of the two AHASL single mutant polypeptides in a single plant. The progeny plants display a synergy with respect to herbicide tolerance, whereby the level of herbicide tolerance in the progeny plants comprising the first and second mutations from the parent plants is

greater than the herbicide tolerance of a plant comprising two copies of the first polynucleotide or two copies of the second polynucleotide.

.... [0058]

<u>Non-transgenic plants comprising the double mutations of AHASL</u> polynucleotides can be produced by methods other than the cross pollination described above, such as, but not limited to, targeted in vivo mutagenesis as described in Kochevenko et al. (Plant Phys. 132: 174-184, 2003). The double mutations can be localized on a single allele, or two alleles of a plant genome."

(A-6) "[0171]

Vector AP1 (Figure 5) is a plant transformation vector that includes the AtAHASL gene with the single S653N mutation (SEQ ID NO: 34). The DNA fragment as shown in SEQ ID No: 34 was cloned into AP1 in the reverse-complement orientation. Vectors AP2- AP7 were generated from AP1 and the AE plasmids using standard cloning procedures and differ only by mutations as indicated in Table 1. For convenience in cloning, different fragments were used to generate Ap6 and AP7, compared to AP2- AP5. Thus, AP6 and AP7 are 47 base pairs shorter than AP1- AP5. This difference is in the plasmid backbone and not the Arabidopsis thaliana genomic fragment."

(A-7) "[0187]

(Example 5)

Plant transformation

The AP vectors were transformed into Arabidopsis (A. thaliana) ecotype Col. 2. The T1 seeds were selected for transformation on plates with 100nM Pursuit ® as the selective agent. T2 seeds from approximately twenty independent transformation events (lines) were plated on MS agar with increasing Pursuit ® concentrations, to score increases in tolerance compared to AP1. The vectors were scored by comparison of the highest concentrations of Pursuit ® having uninhibited growth of seedlings by visual examination. The results of the Arabidopsis transformation experiments are shown in Table 1.

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[0189]

ZP constructs were introduced into maize immature embryos via Agrobacterium-mediated transformation. Transformed cells were selected on selection media supplemented with 0.75 μ M Pursuit ® for 3-4 weeks. Transgenic plantlets were

regenerated on plant regeneration media supplemented with 0.75 μ M Pursuit ®. Transgenic plantlets were rooted in the present of 0.5 μ M Pursuit ®. Transgenic plants were subjected to TaqMan analysis for the presence of the transgene before being transplanted to potting mixture and growth to maturity in a greenhouse. The results of the maize transformation experiments are shown in Table 2. Maize plants transformed with the ZP constructs were sprayed with varying rates of imazamox, in several field locations and in the greenhouse. The relative ratings of the ZP constructs' whole plant test data are summarized in Table 2.

(A-8) "Table 1

【表1】 表1

	シロイヌナズナ (Arabidopsis)		大腸茵 (E.coli)	トランスジェニック植物 耐性:
大腸菌	形質転換		イマゼタビル	AP18(近似値)を超える
プラスミド*	~ / 9 *	突然変異。	耐性スコア"	X倍改善
AE1	AP1	\$653N	+	NA
AE2	AP2	A122TおよびS653N	++	16
AE3	AP3	P197533 & US653N	÷	2
AE4	40.0	A122T、R199A、および	NA	16
	AP8	S653N		
AE5	AP4	R199A、およびS653N	+++	1.5
AE6	AP5	A122 T、 P197S、および S653N	NA	8
AE7		野生型	-(IN)	NA
AE8	AP6	A122TおよびR199A	+++	2
AE9	AP7	A122TおよびP197S	NA	8
AE10		A122T、S57Rおよび S398L	+++	NA
AE11		A122TおよびV139I	++	NA
AE12		A122T#5 L USQ269H	+	NA
AE13		A122TおよびK416M	++	NA
AE14		A122TおよびL426I	+++	NA
AE15		A122T\$3 L UNA430V	+++	NA
AE16		A122TおよびN442I	++	NA
AE17		A122TおよびN445I	++	NA
AE18		A122TおよびN445D	+++	NA
AE19		A122TおよびK580E	+++	NA
AE20		A122T、V439G、D595G 、およびS653N	+	NA
AE21		P197S \$\$ \$ USD375N	+++	NA
AE22		D375N	試験セザキ	NA
AE23		D375N、K83R、V254I、 M277I、およびD315Y	*	NA
AE24		Q95L、K416E、および S653N	+	NA

表1 Table 1

大腸菌プラスミド E.Coli p	lasmid
シロイヌナズナ形質転換ペクター	Arabidopsis transformation vector
突然変異 Mutation	
大腸菌イマゼタピル耐性スコア	E.Coli tolerance score
トランスジェニック植物耐性	Transgenic plant tolerance
(近似値)を超えるX倍改善	X-times improvement exceeding (approximate

8 / 20

value) および and 野生型 Wild type 試験せず Not tested

"

(A-9) "Table 2

【表 2】 表2

大腸菌 プラスミド*	トウモロコシ 形質転換 ベクター*	突然変異·	大腸菌イミダゾリノン 罷性スコア"	トウモロコシ 全植物耐性 スコア&
ZE1	-	S621N	*	NA
ZE2	-	野生型	-(NT)	NA
ZE3	-	野生型	- (NT)	NA
ZE4	ZP1	S621N	+	+
ZE5	-	W542L, \$621N	-(IN)	NA
ZE6	ZP4	P165S, S621N	+	.+
ZE7	-	₩5421.	- (NT)	NA
ZE8	-	M92E, \$621N	-(IN)	NA
ZE9	ZP5	R167S, S621N	.+++	+++
ZE10	ZP2	A90T, \$621N	+++	+++
ZE11	ZP3	A90T, R167S, S621N	+++	+++
ZE12	ZP9	M92I, S621N	***	+++
ZE13		R167A, S621N	NA	NA
ZE14	-	A173V, \$621N	++	NA
ZE15	ZP8	A90T, M92I	+++	+++
ZE16	ZP10	A90T, M92E	NA	NA
ZE17	ZP6	A90T, R167A	+++	+++
ZE18		P165S	- (NT)	NA
ZE19	-	P165S, R167A	-(NT)	NA
ZE20		T1711, \$621N	+	NA
ZE21	ZP7	T06V	++	+++
2622	-	A90T, P165S	+++	NA
ZE23	ZP11	A90Q	+++	+++
ZE24	ZP12	A90Q, M92L	++	+++
ZE25	-	A90Q, M921	+++	NA
ZE26		A90C	++	NA
ZE27	040)	A90M, M92I	+	NA
ZE28		P165E, R167F	- (NT)	NA
ZE29	-	P165V, R167A	- (NT)	NA
ZE30	-	P165E, R167T	+	+
ZE31		P165I, R167D	-(IN)	NA
ZE32	-	P1651, R167E	+	NA
ZE33	-	M921, P165E, R167A	- (NT)	NA
ZE34	-	A90M, P165R, R167C	-(IN)	NA
ZE35	-	M92N, S621G	+++	NA
ZE36	-	P165S, R167N, S621V,	+++	NA

表2 Table 2

大腸菌プラスミドE.Coli plasmidトウモロコシ形質転換ペクターMaize transformation vector突然変異Mutation大腸菌イミダゾリノン耐性スコアE.Coli imidazolinone tolerance score

トウモロコシ全植物耐性スコア 野生型 Wild type

"

B. Cited Document 2

National Publication of International Patent Application No. 2010-523103 indicated in the examiner's decision of refusal dated October 26, 2018 as Cited Document 2 discloses the following matters.

(B-1) "[Claim 1]

<u>A Brassica plant having in its genome at least one copy of acetohydroxyacid</u> <u>synthase large subunit (AHASL) polynucleotide encoding herbicide tolerant AHASL</u> <u>polypeptide</u>, wherein the AHASL polypeptide is selected from a group comprising a) a polypeptide having an asparagine at the position corresponding to position 653 of SEQ ID NO: 1, position 638 of SEQ ID NO: 2, or position 635 of SEQ ID NO: 3, b) a polypeptide having a threonine at the position corresponding to position 122 of SEQ ID NO: 1, position 107 of SEQ ID NO: 4 or position 104 of SEQ ID NO: 5, and c) a polypeptide having a leucine at the position corresponding to position 574 of SEQ ID NO: 1, or position 557 of SEQ ID NO: 6" (Scope of claims)

(B-2) " [Brief description of drawings]

[0019]

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[Figure 2] Wild type AHASL gene from Arabidopsis (AtAHASL, SEQ ID NO: 1), ..."

C. Cited Document 3

National Publication of International Patent Application No. 2009-504137 indicated in the examiner's decision of refusal dated October 26, 2018 as Cited Document 3 discloses the following matters.

(C-1) "[Claim 1]

A sunflower plant having in its genome at least 1 copy of at least 1 type of acetohydroxyacid synthase large subunit (AHASL) polynucleotide, wherein the AHASL polynucleotide encodes <u>herbicide tolerant AHASL protein having a threonine at position</u> <u>107 or a position corresponding thereto</u> and <u>the tolerance for at least one type of herbicide</u> in at least one of the plants is increased compared to wild type sunflower plants" (Scope of claims).

(C-2) "[0184]

Figure 2 shows the alignment of amino-acid sequence foreseen from AHASL 1 nucleic acid sequence of S4897, BTK47, and noogoora burr sp. Compared to AHASL 1 amino-acid sequence of BTK47, a substitution from alanine to threonine has occurred at amino-acid position 7 (SEQ ID NO: 2) in S4897 AHASL 1 amino-acid sequence. This amino-acid position of SEQ ID NO: 2 corresponds to amino-acid position 107 of full-length amino-acid sequence encoded by sunflower AHASL 1 nucleic acid sequence of Genbank registration No. AY541451 (SEQ ID NO: 4), and also corresponds to amino acid position 122 of full-length amino-acid sequence encoded by nucleic acid sequence of Arabidopsis AHASL of Genbank registration No. X51514."

D. Cited Invention

It is acknowledged that Cited Document 1 is a document related to improvement in tolerance for herbicides of plants, and, as stated in A, (A-1) above, the scope of claims of Cited Document 1 discloses, with respect to seeds of the transgenic plant mentioned in Claim 11, regarding AHASL mutation in transgenic plants from various plants as enumerated in Claim 10, mutations enumerated in Claim 1 including specific amino acid substitutions at two positions, one corresponding to position 122 of Arabidopsis AHASL and the other corresponding to position 653.

In addition, as stated in above (A-6) to (A-9), since Cited Document 1 discloses that Arabidopsis was transformed using transforming vector AP2 (A122T and S653N) (Table 1), and that corn was transformed using transforming vector ZP2 (A90T and S621N)(Table 2), it is acknowledged that Cited Document 1 discloses creation of a transgenic Arabidopsis plant in which alanine at position 122 of Arabidopsis AHASL is substituted with threonine, serine at position 653 is substituted with asparagine, and a polynucleotide that encodes Arabidopsis AHASL double mutant polypeptide is included in the genome, and a transgenic corn plant in which alanine at position 90 of corn AHASL (it can be understood from the description in Figure 8 of Cited Document 1 (not excerpted), column for AtAHASL and ZmAHASL 2, that thins position 90 corresponds to position 122 of Arabidopsis AHASL) is substituted with threonine, serine in position 621 of corn AHASL (the same as explained above, it can be understood from Figure 8 that this position 621 corresponds to position 653 of Arabidopsis AHASL) is substituted with asparagine, and a polynucleotide that encodes AHASL double mutant polypeptide of corn is included in the genome. Tables 1 and 2 also disclose that these transgenic plants have an improved tolerance for imidazolinone herbicide tolerance.

In addition, with respect to the amino-acid sequence of AHASL, alignment of Arabidopsis (SEQ ID NO: 1) and various kinds of plants is shown in Figure 3 of Cited Document 1 (not excerpted), and sorghum (Sorghum Bicolor SEQ ID NO: 15) is also shown as one of the various kinds of plants. From this Figure 3, in wide varieties of plant species, alanine is preserved in the position corresponding to position 122 of Arabidopsis AHASL and serine in the position corresponding to position 653.

Then, it is acknowledged that Cited Document 1 discloses the following invention (hereinafter, referred to as the "Cited Invention").

"A seed of a transgenic plant comprising polynucleotide that encodes plant AHASL with mutation of two amino acid substitutions, substitution of alanine at the position corresponding to position 122 of Arabidopsis AHASL with threonine, and serine at the position corresponding to position 653 with asparagine."

(2) Comparison

The invention according to Claim 10 after the amendment (hereinafter, referred to as the "Amended Invention") is compared with the Cited Invention.

According to Figure 3 of Cited Document 1 (especially, Figure 3-2), since position 122 of Arabidopsis AHASL corresponds to position 93 of sorghum (Sorghum bicolor) AHASL (SEQ ID NO: 15), "single substitution from alanine to threonine at position 93 of sorghum AHAS protein large subunit" included in "sorghum grain" of the Amended Invention and "from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL, ... mutation of amino acid substitution" included in "seed of transgenic plant" of the Cited Invention coincide with each other in that they have "an amino acid substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL" in a "plant AHAS protein large subunit."

Accordingly, they are identical in the following point:

"A plant-seed comprising at least one polynucleotide encoding polypeptide having amino acid substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHAS in a large subunit of the plant AHAS protein " and differ from each other in the following points.

(Different Feature 1)

With respect to the kind of plants, while it is specified as "sorghum" in the Amended Invention, it is not specified in the Cited Invention. (Different Feature 2)

With respect to amino acid substitution in plant AHAS protein (AHASL) large subunit, while it is specified in the Amended Invention as "having in the genome at least one polynucleotide encoding a polypeptide having a single substitution from alanine to threonine at position 93 of sorghum AHAS protein large subunit" and that the sorghum AHASL has only a single mutation at position 93 (position corresponding to position 122 of Arabidopsis AHASL), the plant AHASL has the second mutation, mutation from serine at the position corresponding to position 653 of Arabidopsis AHASL to asparagine in the Cited Invention.

(Different Feature 3)

With respect to polynucleotide encoding polypeptide having amino acid substitution, while it is specified in the Amended Invention that such polynucleotide is included in the genome, it is not specified in the Cited Invention.

(3) Judgment

Regarding (Different Feature 1) and (Different Feature 2)

As stated in above (1), A, (A-2), Cited Document 1 discloses that a single mutation, substitution from alanine to threonine at position 100 of cocklebur (Asteracea plant) AHASL (large subunit of AHAS) (Note by the body: It is surmised that "oomomi" is an error of "onamomi (cocklebur)")(position corresponding to position 122 of Arabidopsis AHASL) gives tolerance for imidazolinone and sulfonylurea. In addition, as stated in (A-9) above, Table 2 of Cited Document 1 discloses that tolerance of corn/ZP 7 vector mutant organism that has at AHASL a single mutation, A90T mutation (mutation at the position corresponding to position 122 of Arabidopsis AHASL) is [+++] the same as the tolerance of corn/ZP 2 vector mutant organism that has two mutations, A90T and S621N, and, in addition, further discloses that "it was demonstrated in this specification using Arabidopsis AHASL mutant organism of Arabidopsis (Arabidopsis thaliana) and maize AHASL 2 mutant organism of corn, but its application is not restricted to these genes or to these plants"((A-4) above). In addition, Cited Documents 2 and 3 disclose that, in brassica plants and sunflower, plants that have substitution from alanine to threonine at the position corresponding to position 122 of Arabidosis of AHASL are herbicide tolerant.

Accordingly, it is understood from the statements in Cited Documents 1 to 3 that, in AHASL of various kinds of plants, herbicide tolerance of various plants is improved by introducing a single mutation, substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL.

In addition, it is obvious in inheritable genetic modification of plants that

introduction of single mutation into the gene is simpler than introduction of multiple mutations, and in the case of "substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL," since herbicide tolerance is improved even with only single mutation, a person skilled in the art could have easily conceived to try to create not only plants with multiple mutations but also plants with a single mutation.

Then, with respect to transgenic plants of the Cited Invention, since a person skilled in the art could have easily carried out to identify a "plant that has only a single mutation at the position corresponding to position 122 of Arabidopsis AHASL" instead of plants having a second mutation also, and, in addition, a person skilled in the art could have appropriately carried out to identify from the statements in Cited Document 1 explained in (A-1) and (A-3) above (morokoshi is an alias name of sorghum) sorghum (Sorghum bicolor) as a kind of the plant.

Accordingly, in the Cited Invention, a person skilled in the art could have easily carried out to identify the transgenic sorghum (Sorghum bicolor) that does not have any mutation at the position corresponding to position 653 of Arabidopsis AHASL, but has mutation at the position corresponding to position 122; namely, sorghum comprising polynucleotide that encodes AHASL mutant organism polypeptide having only a single mutation at position 93 of sorghum AHASL.

Therefore, a person skilled in the art could have easily carried out above Different Feature 1 and Different Feature 2.

Regarding (Different Feature 3)

Cited Document 1 recites "As used herein, the term 'transgenic' refers to any plant, plant cell, callus, plant tissue, or plant part that contains all or part of at least one recombinant polynucleotide. In many cases, all or part of the recombinant polynucleotide is stably integrated into a chromosome or stable extra-chromosomal element, so that it is passed on to successive generations" ((A-4) above) and it is acknowledged that "transgenic plants" in the Cited Invention cover not only those transformed by a vector as shown in Tables 1 and 2, but also those in which recombinant polynucleotide is integrated in the chromosome; namely, those having polynucleotide that encodes polypeptide with amino acid substitution in the genome.

Accordingly, Different Feature 3 cannot be deemed to be a substantial different feature.

In addition, since it is obvious that excellent characteristics generated by amino acid substitution are inherited by plants of subsequent generation such as seeds by including a polynucleotide that encodes polypeptide having an amino acid substitution in the genome, a person skilled in the art could have easily carried out specifying that the polynucleotide is included in the genome.

Furthermore, it cannot be acknowledged that any effect that cannot be predicted from the disclosures in Cited Documents 1 to 3 was developed by specifying the kind of the plant to sorghum and specifying a single substitution from alanine to threonine at position 93 for mutation of AHASL in the Amended Invention.

As explained above, since a person skilled in the art could have easily invented the Amended Invention based on the inventions disclosed in Cited Documents 1 to 3, the Amended Invention is not patentable under the provisions of Article 29(2) of the Patent Act.

(4) Appellant's allegation

In the written appeal, the Appellant alleges roughly as follows:

[Allegation A]

It was common technical knowledge as of the filing of the present application that, if the crop differs, the function that changes caused by mutation also differs. In Cited Document 1, a single mutation of substitution from alanine to threonine at position 100 of cocklebur AHASL (Asteracea plant)(position corresponding to position 122 of Arabidopsis AHASL) gives tolerance for imidazolinone and sulfonylurea. On the other hand, "single substitution from alanine to threonine at position 93 of large subunit of sorghum AHAS protein" by the present invention gives tolerance only for imidazolinone and does not give any tolerance for sulfonylurea. This is exemplified by the experimental data of Reference 2.

Accordingly, it cannot be predicted whether the effect of A122T in Arabidopsis can be obtained in sorghum plants by substitution from alanine to threonine at the corresponding position.

[Allegation B]

The transgenic plant disclosed in Cited Document 1 is not any sorghum plant, but a double or triple mutant.

Cited Document 1 discloses that Constructs 6 and 7 that are a double or triple mutant comprising A90T substitution have a higher herbicide tolerance than that of Construct 3 that is a mutant with a single A90T substitution, and, this result gives a person skilled in the art a motivation to choose a double or triple mutant rather than single A90T substitution.

[Allegation C]

From the result of Table 3 of Reference Material 1, it can be understood that the sorghum plant according to the Invention shown in sample No. 5 exhibited a higher tolerance for 2X imidazolinone than that of sorghum plant according to the conventional art, and that it exhibited a higher tolerance for 2X imidazolinone even compared to other plants that have a single mutation, A122T substitution.

Regarding [Allegation A]

It is acknowledged that Cited Documents 1 to 3 demonstrate that a single substitution corresponding to A122T substitution in Arabidopsis AHASL increases tolerance for imidazolinone herbicide not only in cruciferous plants including Arabidopsis, but also in corns, sunflowers, and cockleburs. In addition, as shown in Table 3 of Cited Document 1, in many plant species including sorghum, the position corresponding to position 122 of Arabidopsis AHASL is preserved in alanine, it is natural to consider that mutation to threonine in this position becomes connected with a common phenotype (function), and it can be deemed that a person skilled in the art expects that tolerance for imidazolinone herbicide increases by the substitution also in sorghum compared to wild type.

Since there is such expectation as mentioned above by a person skilled in the art, a person skilled in the art expects from disclosures in Cited Documents 1 to 3 that a sorghum that has the substitution has a tolerance for imidazolinone herbicide. The effect of increasing tolerance for imidazolinone herbicide might not be exactly the same for different kinds of plants, but it can be deemed that a similar effect can be expected, in that the tolerance increases compared to wild type plants that do not have such substitution.

In addition, while paragraph [0015] of the specification of the present application recites "the sorghum plant of the present invention exhibits, compared to wild type sorghum plants, improved tolerance for herbicides, for example, herbicides that target AHAS enzymes, especially imidazolinone and sulfonylurea," it is not stated that a single substitution from alanine to threonine at position 93 of sorghum AHAS gives tolerance for only imidazolinone and does not give any tolerance for sulfonylurea.

Then, the proven data of Reference 2 that a sorghum that has a A93T substitution at sorghum AHASL does not exhibit any tolerance for sulfonylurea, but exhibits tolerance for imidazolinone, exceed the scope that a person skilled in the art can grasp or predict from the disclosure in the present application and it cannot be taken into

consideration as any effect of the inventions according to Claims 1 and 2 of the present application.

In addition, since the proven data of Reference 2 are for a specific strain called [IMI-sorghum (S-M1)], the data cannot be deemed to show the effect developed by the invention as a whole.

Regarding [Allegation B]

As already stated in (3) above, it can be understood from disclosures in Cited Documents 1 to 3 that tolerance of various kinds of plants for herbicide not limited to Arabidopsis and corn can be improved by introducing into AHASL of various kinds of plants a single mutation, "substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL." In addition, since it is obvious in inheritable genetic modification of plants that introduction of a single mutation into the gene is simpler than introduction of multiple mutations, a person skilled in the art could have easily conceived to create in sorghum plants that have a single mutation, "substitution from alanine to threonine at the position 122 of Arabidopsis AHASL."

The Appellant alleges that Cited Document 1 discloses that Constructs 6 and 7 that are double or triple mutant comprising A90T substitution have higher herbicide tolerance than that of Construct 3 that is a mutant with a single A90T substitution, and it is acknowledged that this allegation is made with respect to Table 5 of (Example 7) of Cited Document 1.

In Table 5, however, it is shown that corn plants that have a single mutation, "substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL" have herbicide tolerance, and, as already stated in (3) above, in inheritable genetic modification of plants, since introduction of a single mutation into the gene is simpler than introduction of multiple mutations, a person skilled in the art could have easily conceived to create not only plants with double or triple mutation but also plants with a single mutation.

Regarding [Allegation C]

Since the sorghum plant that is treated as a conventional art in Reference Material 1 has a V560I+W574L substitution (Table 1, S No. 2), but does not have any double substitution comprising A122T, the result in Table 3 cannot be deemed to indicate that the Invention is superior to the Cited Invention.

Accordingly, judging from the disclosure by Reference Material 1, it cannot be

deemed that the Invention develops a special effect.

On the other hand, the result of the experiment in Reference Material 1 shows with respect to A122T substitution mutation that not only sorghum (S-M1) but also sunflower (H-M1), rice (O-M), and corn (Z-M) became herbicide tolerant, and such result does not contradict the judgment in (3) above that "it can be understood from disclosures in Cited Documents 1 to 3 that, in AHASL of various kinds of plants, tolerance for herbicide of various kinds of plants can be improved by introducing a single mutation, 'substitution from alanine to threonine at the position corresponding to position 122 of Arabidopsis AHASL.'"

4. Summary

As explained above, since the invention according to Claim 10 of the scope of claims amended by the Amendment could not have been patented independently at the time of the filing the patent application, and the Amendment does not comply with the provision of Article 126(7) of the Patent Act applied mutatis mutandis by Article 17-2(6) of the Patent Act, it should be dismissed under the provisions of Article 53(1) of the Patent Act applied mutatis mutandis by Article 159(1) of the Patent Act.

No. 3 Regarding the Invention

1. The Invention

Since the Amendment has been dismissed as explained above, the inventions according to Claims 1 to 13 of the present application are the inventions specified by the matters stated in Claims 1 to 13 of the scope of claims amended by the written amendment dated July 11, 2018, and the invention according to Claim 11 among them (hereinafter, referred to as the "Invention") is the invention specified by Claim 11 that is shown in No. 2 above as Claim 11 before amendment.

Then, the Amended Invention restricts "substitution" in the Invention to "single substitution."

2. Reasons for refusal stated in the examiner's decision

Reasons for refusal of the examiner's decision are such that, since the inventions according to Claims 1 to 13 of the present application could have easily been invented by a person skilled in the art prior to the filing of the patent application based on the inventions disclosed in Cited Documents 1 to 3 distributed or an invention that was made publicly available through an electric telecommunication line in Japan or a foreign country prior to the filing of the patent application, they are not patentable under the

provisions of Article 29(2) of the Patent Act. (Cited Documents)

- 1. National Publication of International Patent Application No. 2010-523123
- 2. National Publication of International Patent Application No. 2010-523103
- 3. National Publication of International Patent Application No. 2009-504137

3. As explained in No. 2 above, since the Amended Invention could have easily been invented by a person skilled in the art based on the inventions disclosed in Cited Documents 1 to 3, and, as explained in 1 above, the Amended Invention is an invention that has been restricted, the invention that includes the Amended Invention could have been easily invented by a person skilled in the art based on the inventions disclosed Cited Documents 1 to 3 because of the same ground as that of the Amended Invention.

Accordingly, the Invention is not patentable under the provisions of Article 29(2) of the Patent Act.

No. 4 Closing

As explained above, since the invention according to Claim 11 of the present application is not patentable under the provisions of Article 29(2) of the Patent Act, needless to mention the inventions according to other claims, the present application should be refused.

Therefore, the appeal decision shall be made as described in the conclusion.

April 7, 2020

Chief administrative judge: NAGAI, Keiko Administrative judge: NAKAJIMA, Yoko Administrative judge: KOGURE, Michiaki