April 19, 2023

Third Party Observation under Article 115 EPC

with respect to European Patent applications

i. EP3696188 (Appl. No.: 19157888.9) tiled "GENE FOR RESISTANCE TO PLANT DISEASE" (filed 18.02.2019; priority claims denounced; hereafter "EP1")
ii. EP3927724 (Appl. No.: 19704637.8) tiled "GENE FOR RESISTANCE TO PLANT DISEASE" (resulting from WO2019EP54008 filed 18.02.2019; priority claims denounced; hereafter "EP2")
iii. EP3957168 (Appl. No.: 20191416.5) tiled "PLANT RESISTANCE GENE AND MEANS FOR ITS IDENTIFICATION" (filed 17.08.2020; no priority claimed; hereafter "EP3")

all assigned to KWS SAAT SE & Co. KGaA, Grimsehlstraße 31, 37574 Einbeck / Germany (hereafter "KWS")

The following observations are made with respect to above application:

1. General Observations

Since the applicant denounced the priority, the earliest filing dates for EP1 and EP2 is February 18, 2019. The filing date for EP3 is August 17, 2020. All applications seem to relate to the same subject matter.

EP1 and EP2 are essentially identical in content and solely comprise examples for the creation of the claimed plants by methods of genome editing or transgenic. No deposit of seed material has been made. EP3 describes the creation of Cercospora-resistant varieties by both genome editing and introgression and a deposit has been made.

EP3 was filed 17.08.2020 and claims no priority. The specification of EP3 is essentially equivalent to the US patent US10767191 (US1) of the applicant filed 18.02.2020, which claims priority to WO2020/169178 (filed 18.02.2019) and EP1. However, in contrast to EP1, US1 has additional examples for trait introgression by breeding and equals in that the later filed EP3. While both EP3 and US1 comprise examples for trait introgression by breeding, only EP3 includes a reference to a deposit of seed material.

2. Lack of Novelty

2. 1 Lack of novelty under Article 54(2) EPC for all claims covering plants due to public prior use

KWS recently declared in the PINTO database of the European Seed Association, that applications EP1 and EP3 relate to sugar beet varieties with the denomination names ESCADIA KWS, ADELKA KWS, VIOLA KWS, INSPIREA KWS, BLANDINA KWS, NOVATESSA KWS, MIGUELLA KWS, IMMACULATA KWS, FIAMMETTA KWS, GIACOMINA KWS, BENVENUTA KWS, OTTAVIA KWS, BTS 1740, and REFORMA KWS. For a printout from the PINTO Database see D1, for a reformatted table see D2. According to the Variety Finder of the Community Plant Variety Office (https://vf.plantvarieties.eu/varieties) several of these varieties have an application date for plant variety protection and/or seed marketing authorization in the EU which is prior to the earliest filing date of any of EP1, EP2, and EP3 (see Table 1 below).

Trials for market authorization and/or variety protection purpose are open to inspection by the public, i.e., the public has access to the trials. In consequence, the application date of a variety needs to be considered as the date the varieties with the Cercospora resistance trait have been made available to the public.

Especially the submission of varieties Fiammetta KWS and Giacomina KWS with an application date of Dec. 14, 2017, establishes a novelty destroying prior use against all claims directed to plants or plant cells in EP1, EP2, and EP3.

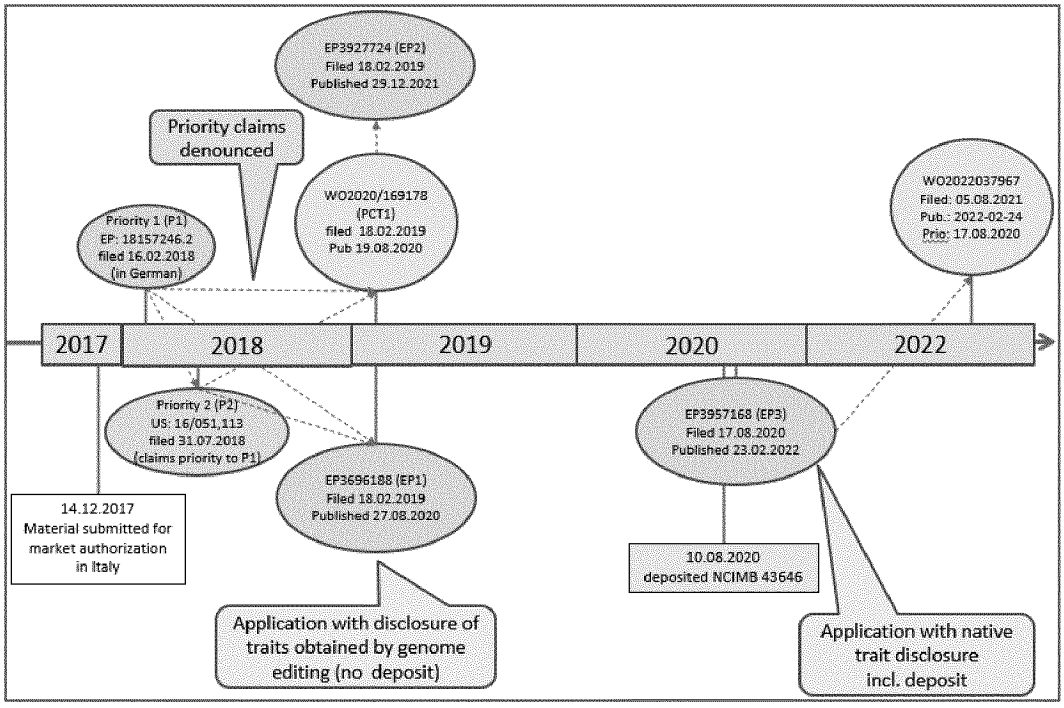
Table 1: Application country, number, and filing date for the varieties listed by KWS on the PINTO database.

	Application Country	Application Number	Application date
Escadia KWS	FR	4066031	13/12/2018
Adelka KWS	PL	R13384	20/12/2018
Viola KWS	IT	020690_A	11/12/2019
Inspirea KWS	FR	4066022	13/12/2018
Blandina KWS	FR	4066023	13/12/2018
Novatessa KWS	DE	ZR 03923	16/12/2019
MIGUELLA KWS	ES	20190058	11/01/2019
IMMACULATA KWS	ES	20200042	13/01/2020
Fiammetta KWS	IT	018854_A	14/12/2017
Giacomina KWS	IT	018845_A	14/12/2017
Benvenuta KWS	IT	019706_A	12/12/2018
Ottavia KWS	IT	019705_A	12/12/2018
BTS 1740	IT	019700_A	12/12/2018
Reforma KWS	BE	RW 030265	14/01/2020

In addition, it is common practice in several application countries (e.g., France) that trials are conducted on the premises of sugar beet breeders. This was – for example – the case for variety Inspirea KWS (application date Dec. 13, 2018). While these trials are conducted under a material transfer agreement (French original D3, available under https://www.geves.fr/wp-content/uploads/PROTOVATEPLANTESDESERVICES20182019.pdf; English translation D4), such trials still establish public use: The user of the materials (usually a breeder) has no limitations to make use of the information learned during the trials. He is entitled to *"marketing of the harvest product (after sampling referred to above) exclusively as a mixture and without indication likely to allow any varietal identification, notwithstanding compliance with other regulations applicable in the species."* Such marketing clearly established a prior use.

Further, marketing materials from KWS (D5) shows commercial use of the variety Fiammetta with a date of March 28, 2000, which is prior to the first filing date of EP3. The timelines of the events are presented in Figure 1 below.

Figure 1:



2.2 Lack of novelty of EP3 over EP1 and EP2 under Article 54(3) EPC

As already found by the examiner in the Communication dated 18.02.2021, EP1 is state of the art with respect to novelty of EP3, pursuant to Article 54(3) and (4) EPC 1973. The nucleic acid molecules (SEQ ID NO: 1-2, 53 or encoding a polypeptide depicted by SEQ ID No.: 3) in EP1 are 100% identical to the sequences of EP3. Applicant KWS has submitted amended claims for EP3. The pending independent claims reads as follows:

> *1. A method for identifying a plant that is resistant or tolerant to Cercospora, characterized in that the method includes detection of at least one marker locus in a cosegregating region, wherein the cosegregating region is a genomic region which cosegregates with the Cercospora resistance conferred by a polypeptide having an amino acid sequence according to, or having at least 90% identity with, SEQ ID No. 3, or with a nucleotide sequence according to, or having at least 90% identity with, SEQ ID No. 1 or 2, and wherein the cosegregating region comprises and is flanked by marker s4pl395s01 and s4p042ls01. [Emphasis added]*

However, EP1 describes also

> *12. Method for identifying, and optionally providing, a plant of the species Beta vulgaris that is resistant to Cercospora, characterized in that the method includes at least step (i) or (ii): (i) detection of the presence and/or expression of the nucleic acid molecule according to claim 1, or the presence of the polypeptide according to claim 2, in the plant or a portion of the plant; and/or (ii) detection of at least one marker locus in the nucleotide sequence of the nucleic acid molecule according to claim 1 or in a cosegregating region, and (iii) optionally selection of the Cercospora-resistant plant, preferably wherein the cosegregating region is a genomic region in Beta vulgaris which cosegregates with the Cercospora resistance conferred by the polypeptide according to claim 2, or with the nucleic acid molecule according to claim 1, more preferably the cosegregating region a) comprises and is flanked by marker sxh0678s01 and s4p0264s01, or b) comprises a sequence according to SEQ ID NO 74 and/or 75. [Emphasis added]*

Based on the declaration on the database PINTO (where both EP1 and EP3 are cited for all sugar beet varieties) it is evident that the introgression described in EP3 is identical to the introgression described in EP1. As the markers cited in pending claim 1 of EP3 are merely used to describe the segregating region (see added emphasis) and not as means for the method of identification, they cannot confer novelty to claim 1. These markers would also be inevitably present in the introgression described in EP1.

2.3. Lack of novelty of plant cell claims

Claim 4 of EP1 and EP2 reads as follows:

> *4. Cell which comprises the nucleic acid molecule according to claim 1 or the polypeptide according to claim 2.*

From the corresponding US application it can be concluded that the resistance-conferring gene is a native trait derived from a wild-type sea-beet accession. While such accession is not disclosed, it must be assumed it is publicly available. As claim 4 is refers to cells in general it would also cover cells of wild-type accession comprising the native trait gene or the resistance-conferring protein expressed therefrom. In consequence, the plant claims would lack novelty.

3. Lack of patentability under Article 53(b) and Rule 28(2) EPC or lack of inventive step

3.1. Sequence Claims

Claim 1 of EP1 as currently pending reads as follows:

1. *Nucleic acid molecule which encodes a polypeptide that is able to confer resistance to Cercospora in a plant in which the polypeptide is expressed, characterized in that the nucleic acid molecule comprises a nucleotide sequence which is selected from*

   (a) a nucleotide sequence that encodes a polypeptide having an amino acid sequence according to SEQ ID No. 3;

   (b) a nucleotide sequence that comprises the DNA sequence according to SEQ ID No. 2;

   (c) a nucleotide sequence that comprises a DNA sequence according to SEQ ID No. 1 or SEQ ID No. 53;

   (d) a nucleotide sequence that hybridizes with a complementary sequence of the nucleotide sequence according to (a), (b), or (c), under stringent conditions, wherein stringent hybridization conditions are: hybridization in 4 x SSC at 65 °C, and subsequent repeated washing in 0.1 x SSC at 65 °C for approximately 1 hour in total;

   (e) a nucleotide sequence that encodes a polypeptide which has an amino acid sequence that is at least 90% identical to an amino acid sequence according to SEQ ID No. 3 over the entire length;

   (f) a nucleotide sequence that is at least 90% identical to a DNA sequence according to SEQ ID No. 1 or SEQ ID No. 2 over the entire length;

   wherein the resistance to Cercospora is a resistance to Cercospora beticola, or the plant belongs to the subspecies Beta vulgaris subsp. vulgaris.

Claim 1 of EP2 reads as follows:

1. *Nucleic acid molecule which encodes a polypeptide that is able to confer resistance to Cercospora beticola in a plant in which the polypeptide is expressed, characterized in that the nucleic acid molecule comprises a nucleotide sequence which is selected from*

   (a) a nucleotide sequence that encodes a polypeptide having an amino acid sequence according to SEQ ID No. 3;

   (b) a nucleotide sequence that comprises the DNA sequence according to SEQ ID No. 2;

   (c) a nucleotide sequence that comprises a DNA sequence according to SEQ ID No. 1 or SEQ ID No. 53;

   (d) a nucleotide sequence that encodes a polypeptide which has an amino acid sequence that is at least 90% identical to an amino acid sequence according to SEQ ID No. 3;

   (e) a nucleotide sequence that is at least 90% identical to a DNA sequence according to SEQ ID No. 1 or SEQ ID No. 2;

   wherein the plant belongs to the subspecies Beta vulgaris subsp. vulgaris.

Claim 1 of EP1 and EP2 as currently pending describes the DNA sequence of a native gene. Due to the absence of the feature "isolated", the claim can be construed to cover the DNA sequence also in a plant in which the sequence was introgressed exclusively by essentially biological processes. Claim 5 of EP1 as currently pending shows that applicant specifically attempts to include plants obtained by introgression i.e., by an essentially biological process.

The grant of such claim could therefore fundamentally undermine the legislative purpose of Rule 28(2) EPC as patentees could by sequencing the causative gene for the "native trait" obtain patents, which might be construed to cover also plants exclusively obtained by an essentially biological process.

In consequence, applicant should be required to either insert the feature "isolated" into claim 1 or to add a disclaimer which is clarifying that the claim is not extending to plants exclusively obtained by an essentially biological process. The preamble of the claim (i.e., "*confer resistance to Cercospora [beticola] in a plant*") in combination with the final "wherein" requirement (i.e., "*wherein the resistance to Cercospora is a resistance to Cercospora beticola, or the plant belongs to the subspecies Beta vulgaris subsp. Vulgaris*" or "*wherein the plant belongs to the subspecies Beta vulgaris subsp. Vulgaris*") make clear that the purpose of this claim is to claim a plant, which should provide a legal basis for such disclaimer. In consequence, the final "wherein" section of an amended claim 1 of EP1 should look as follows:

> *wherein the resistance to Cercospora is a resistance to Cercospora beticola, or the plant belongs to the subspecies Beta vulgaris subsp. Vulgaris, and wherein said plant is not exclusively obtained by means of an essentially biological process.*

Respectively, the final "wherein" section of an amended claim 1 of EP2 should look as follows:

> *wherein the plant belongs to the subspecies Beta vulgaris subsp. Vulgaris, and wherein said plant is not exclusively obtained by means of an essentially biological process.*

3.2. Plant cell claim 4 of EP2

Claim 4 of EP1 and EP2 reads as follows:

> 4. *Cell which comprises the nucleic acid molecule according to claim 1 or the polypeptide according to claim 2.*

As the cell claim does not comprise a requirement that the plant cell is "isolated" and no disclaimer, the cell claims would also cover a plant exclusively obtained by an essentially biological process and would therefore not be patentable under Rule 28(2) EPC.

3.3 Seed claim 5 of EP1

Claim 5 of EP1 as currently pending reads as follows (emphasis added):

> 5. *Seed of a cercospora-resistant plant, characterized in that the plant contains the nucleic acid molecule according to claim 1* ***as introgression*** *or transgenically, wherein the plant which contains the nucleic acid molecule* ***as introgression*** *belongs to the subspecies Beta vulgaris subsp. vulgaris, wherein the seed comprises the nucleic acid molecule according to claim 1 transgenically or as introgression and, wherein the seed has been technically treated, whereby the technical treatment is selected from the group consisting of:*
>
> *(a) Polishing (b) Pelleting (c) Incrustation (d) Colouring.*

The applicant seems to attempt circumventing the exclusion under Rule 28(2) EPC by adding generic and non-inventive features of seed treatment. The attempt seems to be based on a misinterpretation of the EPO's examination guidelines (G-II, 5.4) which provide that *"[t]he technicality of a claimed plant or animal product may lie in a non-heritable physical feature imparted directly to the claimed organism e.g., a seed coated with a beneficial chemical."*[1] However, such approach ignores that in such case the inventive step of the claimed inventions has to be based on this treatment, which is not the case here as the description is generic and unspecific.

Even if the addition could formally circumvent the exception provided by Rule 28(2) EPC, in analogy to decision T 641/00 all features which do not contribute to the technical character of the invention cannot support the presence of an inventive step. The claim explicitly includes versions of the trait obtained by introgression i.e., by exclusively an essentially biological process, which according to G 2/07 is considered to be of a non-technical nature. In consequence, the part of the claim describing the trait

[1] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4.htm

has to be excluded in the assessment of the inventive step which in consequence needs to be assessed solely on the generic and unspecific feature of seed care. Seed care of sugar beet seed is a common practice for decades:

- Polishing of sugar beet seed is for example described in GB9706976D0 (Seed cleaning machine), published 21 May 1997 (D6).
- Pelleting of sugar beet seed is described for example in DE3442317A1 (Verfahren zur Pillierung von pflanzlichen Samen), published 22 May 1986 (D7) and DE2607785A1 (AUFBEREITETES SAATGUT), published 09 Sep 1976 (D8).
- Pelleted and incrustated sugar beet seed is for example described in US20020139046A1 (Seed with a covering which contains a nitrogenous fertilizer) (D9).

In consequence, claim 5 of EP1 has to be considered obvious.

4. Lack of patentability of method of identification claims under G2/07 – G1/08

Claim 10 of EP1 as currently pending reads as follows:

10. Method for identifying a plant of the species Beta vulgaris subsp. vulgaris that is resistant to Cercospora, characterized in that the method includes at least step (i) or (ii):

    (i) detection of the presence and/or expression of the nucleic acid molecule according to claim 1, or the presence of the polypeptide according to claim 2, in the plant or a portion of the plant; and/or

    (ii) detection of at least one marker locus in the nucleotide sequence of the nucleic acid molecule according to claim 1 or in a cosegregating region, and

    (iii) selection of the Cercospora-resistant plant,

    wherein the cosegregating region is a genomic region in Beta vulgaris which cosegregates with the Cercospora resistance conferred by the polypeptide according to claim 2, or with the nucleic acid molecule according to claim 1, and

    a) comprises and is flanked by marker sxh0678s01 and s4p0264s01, or

    b) comprises a sequence according to SEQ ID NO 74 and/or 75.

Similar claims are pending in EP2 and EP3.

Applicant seems to attempt escaping the exception from patentability for essentially biological processes as defined in decisions G 2/07 – G 1/08 by claiming only the step of identification or selection i.e., only the second step of an essentially biological process as defined in G2 /07, which "contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants".

If such claims would be allowable based on an overly literal construction of the G 2/07 decision, it would render the decisions G 2/07 – G 1/08 entirely meaningless, as it is always possible to convert an essentially biological process into a method of identification or method of selection process by omitting the preceding crossing step.

It needs to be noted that a method of identification or method of selection process has only utility if it is applied to a diverse population of plants. Otherwise, no selection is required. Providing such a diverse population inherently requires a step of crossing. In consequence, the claims method of identification is in fact a method of selection which inherently requires a preceding step of sexual crossing and therefore needs to be construed as an essentially biological process according to G 2/07 – G 1 /08. As the preceding crossing is an essential feature it has to be included in the independent claim. See also 1/04 and Examination Guidelines Chapter I.B.4.5.1 d "Clarity of a claim relating to diagnostic methods".

In this context, it also needs to be considered that Article 64(2) EPC provides that "*If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.*" Under Article 8(2) of Directive 98/44/EC such claim could be interpreted to "*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.*"

A "method of identification" or a "method of selection" are processes where the user of the process has a plant in hand at the end of conducting the process. If such processes were allowable, plants obtained by essentially biological processes would be protectable as a product obtained by an identification or selection process. This would render not only G 2/07 – G 1/08 meaningless, but also completely undermine the legislative intent expressed in Rule 28(2) EPC.

5. Lack of sufficiency of disclosure

Applications EP1 and EP2 have been filed with examples exclusively describing the creation of Cercospora-resistant varieties by genome editing.

No deposit of material which would enable the generation of a "native trait" by introgression has been made. No publicly accession is indicated which would enable the generation of a "native trait" by introgression. In consequence, EP1 and EP2 lack written description which enables the person skilled in the art to create a "native trait" version of the Cercospora resistance. At best EP1 and EP2 enable transgenic varieties comprising the described gene. In consequence, attention needs to be paid not to allow any claims on plants which have been exclusively obtained by an essentially biological process.