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Datasheet for the decision of 26 January 2016

Case Number: T 1376/11 - 3.3.04
Application Number: 06734837.5
Publication Number: 1861078

IPC: A61K31/047, A61K31/015, A61K31/381, A01H5/00

Language of the proceedings: EN

Title of invention:
A Capsicum variety exhibiting a hyper-accumulation of zeaxanthin and products derived therefrom

Applicant:
Kalamazoo Holdings, Inc.

Headword:
Paprika plants with orange fruits exhibiting high zeaxanthin concentrations/KALAMAZOO

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - of all requests (no)

Decisions cited:
Catchword:
Decision of Technical Board of Appeal 3.3.04
of 26 January 2016

Appellant: Kalamazoo Holdings, Inc.
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted on 18 January 2011 refusing European patent application No. 06734837.5 pursuant to Article 97(2) EPC.

Composition of the Board:
Chairwoman: G. Alt
Members: M. Montrone
L. Bühler
Summary of Facts and Submissions

I. The appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application No. 06734837. The application was filed as an international application and published as WO 2006/086706 (hereafter "the application") having the title "A capsicum variety exhibiting a hyper-accumulation of zeaxanthin and products derived therefrom".

II. In its decision the examining division dealt with a main and five auxiliary requests. It took the view that the subject-matter of claims 1 of all requests was not disclosed in the application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

III. With the statement of grounds of appeal, the appellant submitted a main request and auxiliary requests 1 to 6. The main request and auxiliary requests 1 to 5 corresponded to the requests dealt with in the decision under appeal.

Claims 1 of the main request and of auxiliary request 3 read:

"1. A Capsicum annuum paprika plant, or regenerable portion thereof, which plant produces orange-coloured ripe fruit pods which exhibit zeaxanthin, wherein the percentage of zeaxanthin relative to total carotenoids [mass zeaxanthin/(mass zeaxanthin plus mass of other carotenoids) x 100] in the dried ripe fruit pod flesh is greater than 50%, when measured in non-esterified forms by High Performance Liquid Chromatography (HPLC),
wherein zeaxanthin has a mass greater than 0.4% by weight of the dry ripe fruit pod flesh, when measured in non-esterified form by HPLC and wherein the dried ripe fruit pod flesh has a moisture content in the range of 1-20 wt%.

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request except that the feature "wherein the percentage of zeaxanthin relative to total carotenoids [mass zeaxanthin/(mass zeaxanthin plus mass of other carotenoids) x 100] in the dried ripe fruit pod flesh is greater than 50%, when measured in non-esterified forms by High Performance Liquid Chromatography (HPLC)" is replaced by the feature "wherein the dried ripe fruit pod flesh has an ASTA value greater than 175 and wherein zeaxanthin is present at a level of greater than 50% of the HPLC area count of the total pigments".

Claim 1 of auxiliary request 2 is identical to claim 1 of the main request except that the feature "obtained by classical plant breeding methods using Capsicum annuum NM 1441 as the parental strain" has been added.

Claims 1 of auxiliary requests 4 and 5 are identical to claim 1 of auxiliary request 1 except that the feature "obtained by classical plant breeding methods using Capsicum annuum NM 1441 as the parental strain" has been added.

Claim 1 of auxiliary request 6 reads:

"1. A plant product in the form of fresh, dehydrated, dried or desiccated fruit pods harvested from a Capsicum annuum paprika plant, or regenerable portion thereof, obtained by classical plant breeding methods using Capsicum annuum NM 1441 as the parental strain, which
plant produces orange-coloured ripe fruit pods which exhibit zeaxanthin, wherein the percentage of zeaxanthin relative to total carotenoids [mass zeaxanthin/(mass zeaxanthin plus mass of other carotenoids) x 100] in the dried ripe fruit pod flesh is greater than 50%, when measured in non-esterified forms by High Performance Liquid Chromatography (HPLC), wherein zeaxanthin has a mass greater than 0.4% by weight of the dry ripe fruit pod flesh, when measured in non-esterified form by HPLC and wherein the dried ripe fruit pod flesh has a moisture content in the range of 1-20 wt%.

IV. The appellant was informed of the board's preliminary view in a communication pursuant to Article 15(1) RPBA. The board observed inter alia that the public availability of commercial Capsicum NM varieties including NM 1441 was doubtful at the priority date (see points 13.1 and 16.2 of the communication) and that it therefore appeared that the requirements of Article 83 EPC were not fulfilled.

V. In reply to the board's communication the appellant submitted inter alia documents D10 and D12 to D14 (see section VI below).

VI. The following documents are referred to in this decision:

D10: Pepper database accession and deposit information sheet for a Capsicum sp. variety designated "1441" from the Aegean Agriculture Research Institute (AARI) disclosing an acquisition date of this variety in the year 2000.
D12: Pepper database accession and deposit information sheet for a *Capsicum annuum* L. variety designated "CAP 1441" from the Genebank, Leibnitz Institute of Plant Genetics and Crop Plant Research disclosing an acquisition date in the year 1971.

D13: Pepper database accession and deposit information sheet for a *Capsicum annuum* L. variety designated "CAP 1441" from the IPK Gatersleben.

D14: Declaration by Dr. Young of 22 December 2015

VII. Oral proceedings before the board were held on 26 January 2016. At the end of the oral proceedings the chairwoman announced the board's decision.

VIII. The appellant's arguments may be summarised as follows:

*Sufficiency of disclosure (Article 83 EPC)*

*Main request and auxiliary requests 1 to 6*

The paprika plant of the invention was reliably obtained by growing the paprika variety *Capsicum annuum NM 1441* as a parental source material. No supply source for this variety was disclosed in the application. However, the skilled person would have complemented the information of the application with common general knowledge about standard plant seed suppliers, such as depository institutions. With some trial and error, by using 1441 and *Capsicum* as search terms in the databases of different depository institutions, he would have found a *Capsicum sp.* variety denoted as 1441 and deposited in the year 2000 (document D10) and a *Capsicum annuum* L. variety CAP 1441 deposited in the year 1971.
(document D12). At least one of the documents explicitly indicated that a *Capsicum annuum* L. CAP 1441 paprika variety was available for ordering and represented a traditional cultivar (document D13). The latter implied that the CAP 1441 variety was available to the public also outside of plant depositories. Accordingly, it was plausible that the varieties disclosed in documents D10, D12 and D13 were publicly available, since the main purpose of depository institutions was the long-term preservation of plant varieties and the reliable supply of plant breeders with seed material on demand.

Moreover, it was sufficiently plausible that the parental NM 1441 variety of the application was identical to the 1441 variety reported in document D10 and to the CAP 1441 varieties disclosed in documents D12 and D13. This was derivable from the consistent disclosure of the number 1441 in all these prior art documents and the application, and because this number was also used by the inventor in the context of the parental strain (document D14). Also, there were no indications that the 1441 was arbitrarily allocated to these paprika plants by the depository institutions. Therefore, the designation NM 1441 was considered implicit in 1441 and CAP 1441.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, of one of auxiliary requests 1 to 6, all filed with the statement setting out the grounds of appeal.
Reasons for the Decision

Sufficiency of disclosure (Article 83 EPC)

Main request – claim 1

1. For the requirement of sufficiency of disclosure to be fulfilled the European patent application "shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" (Article 83 EPC).

2. It is further established case law that an invention must be sufficiently disclosed at the effective date of the application, and that the common general knowledge of the skilled person may be taken into account for supplementing the information disclosed. Also, the application has to disclose at least one way enabling the skilled person to carry out the invention without undue burden (see Case Law of the Boards of Appeal of the EPO, 7th edition 2013, section II.C).

3. The invention concerns Capsicum annuum, i.e. paprika plants, with orange-coloured fruits that exhibit a zeaxanthin composition in amounts and percentages relative to other carotenoids as defined in claim 1.

4. The application discloses that the paprika plants of the invention "are the product of a plant breeding program using classical plant breeding methods of hybridization, single plant selection and progeny row evaluation" (see paragraph [00114]). The sole working example relating to the first step of this program indicates that "a commercial Capsicum annuum variety NM plant type as a
source of plant breeding material" is used (see paragraph [00180]; emphasis added by the board).

Suitable NM source varieties reported are "Capsicum plants exhibiting high zeaxanthin concentrations in the mature fruits [which] can predictably be bred using a commercially grown NM variety, such as 1441, as a parental strain" (see paragraph [00182]; emphasis added by the board).

The frequency and reliability of arriving at the paprika plants of the invention are further reported as "Obtaining a Capsicum plant with the desired zeaxanthin composition by using the breeding methods described herein is a relatively rare, but a repeatable event. For example, 5 Capsicum plants exhibiting high concentrations of zeaxanthin in the ripe fruit pod flesh were obtained after evaluation of about 102,000 plants in a test plot" (see paragraph [00182]; emphasis added by the board).

5. In the board's view, the skilled person would derive from the passages of the application cited above that about one paprika plant with the desired properties will spontaneously arise, i.e. without artificial mutagenesis, after growing about 20,000 plants of wild-type NM parental varieties of Capsicum annuum, e.g. 1441, as source plants. The rare and spontaneous appearance of paprika plants with the claimed properties would further imply to the skilled person that the parental NM varieties are characterised by a unique genetic instability which inevitably excludes all other Capsicum annuum varieties as potential parental plants for reproducing the invention.
6. Therefore, the board concludes that the only way disclosed in the application to arrive at the plants of the invention starts from parental *Capsicum annuum* NM varieties, such as *Capsicum annuum* NM 1441. The public availability of these parental plants at the priority date of the application is therefore a mandatory requirement for the skilled person to reproduce the invention.

7. The wild-type *Capsicum annuum* NM parental varieties disclosed in the application including *Capsicum annuum* NM 1441 are only characterised by their NM designation and the red colour of their fruits (see paragraph [00181]). Red-coloured paprika fruits are, however, very common in paprika plants and therefore not a characteristic feature of NM varieties. Accordingly, the NM designation, in particular in combination with the number 1441, is the sole feature identifying the parental plants. Other information which would enable the skilled person to have access to these parental NM strains, for example concerning commercial or non-commercial supply sources, a deposit pursuant to Rule 31 EPC or the genetic origin(s) responsible for the observed instability, is neither disclosed in the application nor derivable from the available prior art documents. This has also not been contested by the appellant.

8. According to the case law, the skilled person may supplement the information of the application regarding the NM plants by common general knowledge (see point 2 above). In the board's view, the skilled person in the present case is familiar with breeding and cultivating plants, such as paprika, and would certainly also be aware of commonly known supply sources of plant seeds, such as depository institutions.
9. The sole feature disclosed in the application characterising the parental paprika NM varieties is their designation (see point 7 above). Therefore, in the board’s view, the skilled person would use NM 1441 as a search term to look for the parental plants in databases or catalogues inter alia of depository institutions.

10. The appellant has submitted no evidence that a search at the effective date of the application with the search term NM 1441 would have provided the skilled person with the desired parental plant material. The board therefore concludes that the skilled person would not have found a supply source by a search based on the designation NM 1441 disclosed in the application.

11. In the board’s view, the skilled person faced with the initial failure to find a supply source for NM 1441 would certainly have tried simple modifications of the search strategy, such as the use of the term 1441 without NM in combination with Capsicum, and then repeated the search. By following this approach he would have found documents D10, D12 and D13, all disclosing deposit information about Capsicum plants in three depository institutions.

12. The paprika plants disclosed are a Capsicum sp. 1441 deposited in the year 2000 (see document D10) and a Capsicum annuum L. CAP 1441 deposited in the year 1971 (see document D12). A further Capsicum annuum L. CAP 1441 is disclosed in document D13. None of these documents explicitly discloses NM 1441. Under these circumstances it has to be assessed whether it can be ascertained that Capsicum annuum NM 1441 is identical to any of the paprika strains disclosed in documents D10, D12 and D13.
13. The appellant submitted that this was "sufficiently plausible" due to the consistent disclosure of the number 1441 in the application and in documents D10, D12 and D13.

14. The board notes, however, that with the exception of the mere 1441 number, no other information is available which supports the possibility of all these paprika plant varieties being identical. On the contrary, document D10 for example reports the number 1441 in the context of a Capsicum sp., i.e. a Capsicum species which comprises all known species of Capsicum, whereas documents D12 and D13 disclose the specific species Capsicum annuum L.. Moreover, documents D10 and D13 disclose different donors of the deposited plants and while documents D12 and D13 indicate Turkey as country of origin, no such information is derivable from document D10. Also, neither the application nor any other evidence filed by the appellant discloses details about the origins or the commonness of the NM nomenclature for paprika plants, which means that it cannot be excluded that Capsicum annuum NM 1441 is a mere internal designation used solely in the application.

15. In view of the evidence on file, the board concludes that it cannot be ascertained whether the Capsicum annuum NM 1441 variety disclosed in the application is identical to the paprika plants denoted as 1441 in document D10 or as CAP 1441 in documents D12 and D13. Accordingly, the argument of the appellant that all these plants are identical is not convincing to the board.
16. Moreover, and independently of the identity issue considered above, the board is not convinced by the evidence on file that any of the three paprika plant varieties disclosed in documents D10, D12 or D13 was in fact available to the public before the priority date of the application, as argued by the appellant.

16.1 Document D10 discloses a *Capsicum sp.* with the number 1441 which was deposited in the year 2000, but is silent as whether seeds of this plant could be ordered.

16.2 Document D12 discloses a *Capsicum annuum* plant denoted as CAP 1441 and the year 1971 as the acquisition date. However, the availability status of this plant is indicated as "Unknown".

16.3 Document D13 also reports on a *Capsicum annuum* variety denoted as CAP 1441. This strain is available for ordering, but the date when this became possible is not disclosed. Nor, in the board's view, is the reference to a "traditional cultivar" evidence that the plant was indeed commonly available before the priority date of the application, since its cultivation could have been abandoned, e.g. for commercial reasons because other varieties producing higher fruit yields were available.

16.4 In view of the above considerations, the board concludes that the disclosure of documents D10, D12 or D13 does not establish that paprika varieties with the designation 1441 or CAP 1441 were in fact publicly available at the priority date of the application.

17. In summary, the board therefore concludes that the paprika plants 1441 and CAP 1441 of documents D10, D12 and D13 are neither identical to the *Capsicum annuum*
NM 1441 disclosed in the application, nor were they publicly available before the priority date.

18. The board has already established that the public availability of the paprika variety *Capsicum annuum* NM 1441 before the priority date is a mandatory requirement for sufficient disclosure in the application, of the paprika plants of the invention (see point 6 above). Therefore, in the absence of evidence that *Capsicum annuum* NM 1441 was publicly available, the board concludes that the application does not disclose the subject-matter of claim 1 in a manner sufficiently clear and complete for it to be carried out by the skilled person. Accordingly, the main request does not fulfil the requirements of Article 83 EPC.

**Auxiliary requests 1 to 6 - claim 1**

19. Claim 1 of auxiliary request 3 is identical to claim 1 of the main request. Accordingly, the reasons provided in points 6 to 18 above apply *mutatis mutandis* to the subject-matter of this claim.

20. Claims 1 of auxiliary requests 1, 2, 4 and 5 all relate - like claim 1 of the main request - to paprika plants with orange fruits of defined properties. Claim 1 of auxiliary request 6 relates to plant products harvested from a *Capsicum annuum* that was "obtained by classical plant breeding methods using *Capsicum annuum* NM 1441 as the parental strain" with orange fruits having identical properties to those of claim 1 of the main request.

21. Compared to the subject-matter of claim 1 of the main request, the amendments made in claims 1 of auxiliary requests 1, 2 and 4 to 6 essentially concern the
introduction of an ASTA value as a selection marker for the orange colour intensity (auxiliary requests 1, 4 and 5) and/or the introduction of a product-by-process feature (auxiliary requests 2 and 4 to 6), or relate to plant products instead of plants (auxiliary request 6).

22. These amendments do not change the essence of the invention defined in claim 1 of the main request, i.e. paprika plants with orange fruits that exhibit defined zeaxanthin concentrations in an amount and relative percentage to other carotenoids. This applies to the plants of claims 1 of auxiliary requests 1, 2, 4 and 5 and to the plant products of claim 1 of auxiliary request 6.

23. Accordingly, the reasoning set out in points 6 to 18 above applies mutatis mutandis to the respective claims 1 of auxiliary requests 1 to 6. Hence, none of these requests is allowable and they likewise do not fulfil the requirements of Article 83 EPC.
Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated