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# Datasheet for the decision of 25 June 2021

T 0037/19 - 3.3.05 Case Number:

10784066.2 Application Number:

Publication Number: 2437869

IPC: B01D59/44, C12P21/06, C07K1/36,

G01N33/68

Language of the proceedings: ΕN

#### Title of invention:

MULTIPLEX ANALYSIS OF STACKED TRANSGENIC PROTEIN

## Patent Proprietor:

Dow AgroSciences LLC

#### Opponents:

- 1.BASF Plant Science Company GmbH
- 2. Syngenta Crop Protection AG

#### Headword:

Multiplex Analysis/Dow AgroSciences

# Relevant legal provisions:

EPC Art. 123(2), 104 RPBA 2020 Art. 13(2), 11

# Keyword:

Amendments - added subject-matter (yes) - main request - added subject-matter (no) - auxiliary request

Amendment after summons - exceptional circumstances (yes)

Apportionment of costs - (no)

Remittal - (yes)

# Decisions cited:

T 0213/14

# Catchword:



# Beschwerdekammern Boards of Appeal Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY

Tel. +49 (0)89 2399-0 Fax +49 (0)89 2399-4465

Case Number: T 0037/19 - 3.3.05

DECISION
of Technical Board of Appeal 3.3.05
of 25 June 2021

Appellant: Dow AgroSciences LLC

(Patent Proprietor) 9330 Zionsville Road

(Patent Proprietor) S330 Z10NSVIIIe Road Indianapolis IN 46268-1054 (US)

Representative: HGF

1 City Walk

Leeds LS11 9DX (GB)

Respondent 1: BASF Plant Science Company GmbH

(Opponent 1) 67056 Ludwigshafen (DE)

Representative: Altmann Stößel Dick Patentanwälte PartG mbB

Dudenstrasse 46 68167 Mannheim (DE)

Respondent 2: Syngenta Crop Protection AG

(Opponent 2) Rosentalstrasse 67 4058 Basel (CH)

Representative: SYNGENTA IP

CHBS-B4.8

Rosentalstrasse 67 4058 Basel (CH)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 11 October 2018 revoking European patent No. 2437869 pursuant to

Article 101(3)(b) EPC.

# Composition of the Board:

O. Loizou

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# Summary of Facts and Submissions

I. The patent proprietor's (appellant's) appeal lies from the opposition division's decision to revoke European patent No. B-2 437 869.

The opposition division found that the ground of opposition under Article 100(c) EPC was prejudicial to the patent as granted; then auxiliary requests 1 to 3 were not admitted into the proceedings.

- II. In the communication pursuant to Article 15(1), the board expressed its preliminary opinion that the appeal was likely to be dismissed.
- III. The appellant submitted a new auxiliary request 4 on 8 April 2021.
- IV. During oral proceedings of 25 June, the appellant withdrew auxiliary requests 1 to 3. Independent claim 1 of the main request (patent as granted) is as follows:
  - "1. A high throughput method of detecting the presence of two or more proteins of interest with known amino acid sequences in a plant based sample from a transgenic plant, the method comprising:
  - i) providing mass spectral data for two or more proteins that are expected products of transgene expression in the transgenic plant;
  - ii) providing a first injection of complex plant based sample comprising proteins, wherein the sample is a crude plant matrix extracted from a tissue of interest; iii) contacting the crude plant matrix with a protease to digest proteins to peptides;

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- iv) injecting the digested crude plant matrix into an LC-MS device;
- v) obtaining simultaneous mass spectral data for the peptides;
- vi) comparing the simultaneous mass spectral data of v) to the mass spectral data provided for the two or more proteins of interest, thereby determining the presence or absence of the two or more proteins of interest."

The only amendment in claim 1 (underlined) of the auxiliary request, as compared with claim 1 of the main request, is in step iv, which reads as follows:

"iv) injecting the digested crude plant matrix into an LC-MS/MS device"

V. The appellant's arguments relevant to the present decision can be summarised as follows.

The requirements of Article 123(2) EPC were met for the main request. Paragraph [0066] as originally filed would have provided a clear and unambiguous basis for the skilled person reading the claim with a mind willing to understand the amendment made in claim 1 relating to the crude plant matrix. It would have been evident from the whole teaching of the application as filed that any purification was optional and not essential to practising the invention.

Step vi) also allowed for the absence of the proteins of interest. Purification was possibly required if the method of claim 1 executed with the crude plant material did not provide the desired results. This was completely analogous with COVID-19 testing.

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The auxiliary request was to be admitted. It was an easily comprehensible and straightforward reaction to the board's preliminary opinion that clearly differed from the opposition division's interpretation.

VI. Respondents 1 and 2's (opponents 1 and 2's) arguments can be summarised as follows.

The last sentence of paragraph [0066] indicated that a purification of the crude plant material was required in specific cases, as confirmed by example 4. The fact that this purification step was missing from claim 1 constituted an intermediate generalisation that infringed Article 123(2) EPC.

The auxiliary request was not to be admitted. Reference to LC-MS/MS had already been made in respondent 1's statement of opposition. The amendment made in claim 1 of the auxiliary request could have been made much earlier. In fact, requests containing such an amendment had previously been on file but had subsequently been withdrawn. There was no change of case, so there was no justification for the request at such a late stage. In any case, the proposed wording did not address the issue relating to the mandatory purification step.

According to respondent 1, the submission of the auxiliary request at such a late stage required a reaction by the other parties that involved costs. This justified an apportionment of costs.

VII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the opposition be rejected (main request) or, alternatively, that the patent be maintained in amended form on the basis of the sole auxiliary request

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previously filed by letter dated 8 April 2021 as auxiliary request 4.

Respondent 1 (opponent 1) requested that the appeal be dismissed. Furthermore, it requested a remittal of the case to the opposition division if the requirements of Article 123(2) EPC were found to be met. With its letter dated 27 April 2021, it requested apportionment of costs if auxiliary request 4 was admitted and the case was remitted to the opposition division.

Respondent 2 (opponent 2) requested that the appeal be dismissed.

# Reasons for the Decision

Main request (patent as granted)

# 1. Article 123(2) EPC

The only point of debate is whether it would have been directly and unambiguously derivable from the application as filed (WO-A2-2010/141674) that a crude plant matrix can be used in the method of claim 1.

The opposition division was of the opinion that this was not the case under all circumstances since paragraph [0066] of the application as filed disclosed in the last sentence that partial purification of such a crude plant matrix was required in some cases to allow detection of the peptide fragments (point 9 of the Reasons of the decision under appeal).

Claim 1 relates to a "method of detecting", the wording of which is based on claim 12 as filed or paragraph

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[0010] of the application as filed. The primary goal of the method is to detect two or more proteins of interest, even though step vi) indicates that the proteins of interest may possibly be absent.

Paragraph [0066] discloses that the crude plant matrix can be analysed either directly or after purification depending on the detection sensitivity ("if target detection requires"). The skilled person would have known from the application that mass spectrometry methods as indicated in paragraph [0051] are the methods of choice for the detection of the peptides. Paragraph [0068] teaches that a complex protein sample subjected to MS/MS multiplex analysis does not need to be as pure or abundant as a sample to be analysed by conventional techniques (PCR or immunochemistry). A crude plant matrix would have been considered a complex protein sample by the skilled person.

In addition, paragraph [0074], last sentence, teaches that MS/MS is an extremely powerful analytical technique.

Reading these paragraphs in combination with the last sentence of paragraph [0066], the skilled person would have understood that tandem mass spectrometry is the detection method to be used when complex samples are to be analysed without purification with the goal of detecting the proteins of interest. This understanding is completely in line with the figures, which are all based on tandem mass spectrometry (see paragraphs [0013] to [0022]) and examples I to VII.

There is no direct and unambiguous disclosure in the application as filed from which it could be concluded that any LC-MS method allows analysing any crude plant

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matrix while making it possible to detect the proteins of interest.

Paragraph [0002] cited by the appellant does not relate to detecting; paragraph [0009] is silent on mass spectrometry; and paragraph [0011] does not provide any indication of a crude plant matrix. Paragraph [0051] refers to mass spectrometry in general and refers "inter alia" to tandem MS while paragraph [0058] only defines "single injection". Neither paragraph [0051] nor paragraph [0058] discloses that all mass spectrometry methods are sufficient for detecting the proteins of interest in a crude plant matrix. Paragraph [0070] only explains the difference between MS and MS/MS without disclosing that MS analysis is sufficient as a detection method irrespective of the sample.

Therefore, all that would have been directly and unambiguously derivable from the application as originally filed is that peptides from any crude plant matrix can be detected via tandem mass spectrometry.

Since this indication is not present in claim 1, the requirements of Article 123(2) EPC are not fulfilled.

# Auxiliary request

#### 2. Article 13(2) RPBA 2020

This request was submitted after the notification of the communication pursuant to Article 15(1) RPBA 2020. In the present case, Article 13(2) RPBA 2020 applies (see Article 25(3) RPBA 2020).

The auxiliary request is considered to constitute an amendment to the appellant's appeal case. Such an

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amendment must, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

In the present case, the board accepts that there are exceptional circumstances which justify the late filing by the appellant.

Although there had been requests that contained the limitation to LC/MS-MS throughout the opposition proceedings, these requests contained other amendments that were evidently not allowable, so their withdrawal was a logical step for the appellant which helped procedural economy. A request identical to the current one has never previously been part of the proceedings.

The board's preliminary analysis in the communication pursuant to Article 15(1) RPBA 2020 differed from the opposition division's assessment in point 9 of the Reasons of the decision under appeal, and the board also did not fully accept the respondent's line of argument. It was not possible for the appellant to anticipate this position, so the auxiliary request is a legitimate reaction to the way the situation had changed in view of the preliminary opinion.

In addition, the amendment to the wording of claim 1 is a minor one that is easy to understand and overcomes the objection under Article 123(2) EPC without giving rise to objections under Article 84 EPC or Article 123(3) EPC.

Therefore, the board decided to take the auxiliary request into account.

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# 3. Article 123(2) EPC

The amendment overcomes the deficiency in the main request.

The board does not share the respondents' view that a crude plant matrix may require a purification step prior to detecting the proteins of interest. As set out in the reasoning for the main request above, the application as filed directly and unambiguously discloses that LC-MS/MS allows for this detection in a crude plant matrix even without the need for further purification.

Example 4 does not contradict this conclusion based on the disclosure of the description. Rather, it shows the effect of different extraction methods on the detection of the different proteins. It does not teach that LC-MS/MS does not allow for detecting proteins of interest when specific extraction methods are used but illustrates that some extraction methods may be more powerful than others when trying to detect certain proteins from specific samples.

The question whether the samples extracted in urea or PBS-T buffer required a mandatory purification step is therefore irrelevant for deciding on the Article 123(2) EPC objection.

The requirements of Article 123(2) EPC are met.

# 4. Article 104 EPC and Article 16 RPBA 2020

Article 16(1) RPBA 2020 allows the board, subject to Article 104(1) EPC, to order a different apportionment

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of costs on request. Respondent 1 based its request on Article 16(1)(a) RPBA 2020 (amendment to a party's appeal case pursuant to Article 13).

A relevant factor in deciding on the costs is whether there are cogent reasons justifying the late submission (Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, III.R.2.1).

The board decided under Article 13(2) RPBA 2020 above that there were cogent reasons for the late submission of the auxiliary request.

In addition, a proprietor filing new requests to defend its position after oral proceedings have been scheduled or on receiving a negative preliminary opinion of the board is not an extraordinary circumstance justifying an apportionment of costs (T 213/14, Reasons 4.2.1).

Therefore, the late submission does not justify an apportionment of costs, and the request for this is refused.

# 5. Article 11 RPBA 2020

As indicated in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner.

In the case at hand, the contested decision exclusively dealt with the requirements of Article 123(2) EPC and the admissibility of the then auxiliary requests. Patentability was not discussed.

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As a result, there can be no judicial review of any issues other than those under Articles 123(2) and (3) and 84 EPC. Thus, there are "special reasons" within the meaning of Article 11 RPBA 2020 for a remittal to the opposition division for further prosecution.

# Order

# For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the opposition division for further prosecution on the basis of the sole auxiliary request previously filed by letter dated 8 April 2021 as auxiliary request 4.

The Registrar:

The Chairman:



A. Voyé E. Bendl

Decision electronically authenticated