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**Datasheet for the decision  
of 5 December 2024**

**Case Number:** T 0582/22 - 3.3.08

**Application Number:** 11189292.3

**Publication Number:** 2439267

**IPC:** C12N9/38, A23C9/12, C12N9/62,  
C12N15/55

**Language of the proceedings:** EN

**Title of invention:**  
Enzyme preparations yielding a clean taste

**Patent Proprietor:**  
DSM IP Assets B.V.

**Opponent:**  
NOVOZYMES A/S

**Headword:**  
Process for preparing a lactase preparation/DSM IP Assets B.V.

**Relevant legal provisions:**  
EPC Art. 100(c), 76(1)

**Keyword:**  
Main request, auxiliary requests 1 to 4 - added subject-matter  
(yes)

**Decisions cited:**

G 0001/05, G 0002/10



**Beschwerdekammern**

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Case Number: T 0582/22 - 3.3.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 5 December 2024**

**Appellant:** DSM IP Assets B.V.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 3 January 2022  
revoking European patent No. 2439267 pursuant to  
Article 101(3) (b) EPC**

**Composition of the Board:**

**Chairwoman** T. Sommerfeld  
**Members:** R. Morawetz  
D. Rogers

## **Summary of Facts and Submissions**

- I. European patent No. 2 439 267 ("the patent") was granted on European patent application No. 11 189 292.3 which was filed as a divisional application in respect of earlier European patent application No. 06 819 802.7 which was filed as an international application under the PCT and published as WO 2007/060247 ("the earlier application", document A1 in the proceedings). The patent is entitled "Enzyme preparations yielding a clean taste".
- II. An opposition was filed against the patent, which was opposed under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC.
- III. The opposition division revoked the patent. In the decision under appeal, the opposition division considered a main request (patent as granted) and sets of claims of auxiliary requests 1 to 4. The opposition division held, *inter alia*, that the main request met the requirements of Articles 123(2) and 76(1) EPC but contravened Article 56 EPC; that auxiliary request 1 contravened Article 56 EPC for the same reasons as the main request; that auxiliary requests 2 and 3 contravened Articles 123(2) and 76(1) EPC and that auxiliary request 4 contravened Article 56 EPC.
- IV. The patent proprietor (appellant) appealed against the opposition division's decision.
- V. With its statement setting out the grounds of appeal, the appellant maintained the patent as granted as its main request and submitted sets of claims of auxiliary

requests 1 to 4.

Claim 1 of the main request reads as follows:

"1. A process for preparing a lactase preparation comprising

- a. using mutagenesis conditions or recombinant genetic manipulation techniques on a culture which produces arylsulfatase such that part of the culture is modified to form an arylsulfatase deficient host cell, in which the parent host cell comprises one or more nucleotide sequences encoding arylsulfatase and the mutant host cell produces less arylsulfatase activity than the parent cell when cultured under the same conditions; and isolating the host cell;
- b. cultivating said host cell in a nutrient medium, under conditions conducive to expression of the lactase and expressing the lactase in said host cell; and
- c. recovering the lactase from the nutrient medium or from the host cell."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "wherein the host cell is a *Kluyveromyces* host cell" is added at the end of the claim.

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the feature "wherein the host cell is a *Kluyveromyces lactis*, *Kluyveromyces marxinus* or *Kluyveromyces fragilis* host cell" is added at the end of the claim.

Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the feature "wherein the host cell is a *Kluyveromyces lactis* host cell" is added at the end of the claim.

- VI. In its reply to the statement of grounds of appeal, the opponent (respondent) maintained that, contrary to the decision of the opposition division, claim 1 of the main request added matter and that the objection was not overcome by any of the amendments to claim 1 of auxiliary requests 1 to 4.
- VII. The board scheduled oral proceedings, in accordance with the parties' requests, and issued a communication under Article 15(1) RPBA.
- VIII. The parties' submissions, in so far as they are relevant to the present decision, are discussed in the reasons for the decision.
- IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, alternatively, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 4.

The respondent requested that the appeal be dismissed and that the case be remitted to the opposition division for further prosecution if the appeal was allowed.

## **Reasons for the Decision**

### *Main request*

*Added subject-matter (Article 100(c) in conjunction with Article 76(1) EPC)*

1. The standard for assessing compliance with the requirements of Articles 123(2) and 76(1) EPC is the same (see G 1/05, OJ EPO 2008, 271, Reasons 5.1), namely the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also known as the "gold standard". Amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier application as filed. After the amendment, the skilled person may not be presented with new technical information (*ibid.*, Reasons 4.5.1).
2. It is well established in the case law of the boards of appeal that the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined in order to artificially create a particular embodiment. In the absence of any pointer to the claimed combination of features, the combined selection of features does not emerge clearly and unambiguously from the content of the application as filed for the person skilled in the art (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, "Case Law", II.E.1.6.1(a)).
3. Reference is made below to the page and line numbering of the earlier application (document A1), referred to

as the "application as filed".

4. Claim 1 of the main request relates to a process for preparing a lactase preparation comprising as a first step *"using mutagenesis conditions or recombinant genetic manipulation techniques on a culture which produces arylsulfatase such that part of the culture is modified to form an arylsulfatase deficient host cell, in which the parent host cell comprises one or more nucleotide sequences encoding arylsulfatase and the mutant host cell produces less arylsulfatase activity than the parent cell when cultured under the same conditions; and isolating the host cell"* (step a.). Further steps of the method relate to cultivating the host cell in a nutrient medium (step b.) and expressing the lactase in the host cell and recovering the lactase from the nutrient medium or from the host cell (step c.).
5. The opposition division held that steps b. and c. of the process of claim 1 of the main request were based on the combination of claims 29 and 33 to 35 of the application as filed, wherein one selection has been made of lactase from the list of four enzymes in claim 35 of the application as filed. Step a. of the process which is directed to the production of the arylsulfatase deficient host cell was considered to be based on claims 26 to 28 of the application as filed or, alternatively, on page 17, lines 25 to 33 of the application as filed. The definition of the feature "arylsulfatase deficient" was held to find a basis on page 29, lines 4 to 9 of the application as filed.
6. The incorporation of the subject-matter of claims 26 to 28 of the application as filed into the process of independent claim 29 of the application as filed was



justified as follows: "[s]ince the method of claim 29 of A1 uses an arylsulfatase deficient host cell, the process of claims 26 to 28 for producing an arylsulfatase deficient host cell may be combined therewith without contravening Article 76(1) EPC" (decision under appeal, Reasons 2.2.1).

7. For the following reasons, the board agrees with the respondent that the decision under appeal is incorrect on this point.
8. The board observes that when assessing the requirements of Article 76(1) EPC there is no room for speculation as to which features the skilled person might consider combining. Such speculations relate to obviousness.
9. Instead, the relevant question to be addressed is whether a skilled person would seriously contemplate the combination of features disclosed in the application for different embodiments because of an - explicit or implicit - indication in the application as filed that the specific combination is envisaged (Case Law, II.E.1.6.1(a) and decisions cited therein).
10. In that context the board observes that claims 26 and 29 of the application as filed relate not only to separate embodiments but to fundamentally different types of processes. Thus, claim 26 concerns a "*[p]rocess to produce a host cell which is an arylsulfatase deficient strain, which comprises bringing a culture which produces arylsulfatase under conditions that part of the culture is modified to form the host cell which is arylsulfatase deficient and isolating the host cell*" while claim 29 concerns "*[a] process to produce a polypeptide by a method comprising (a) cultivating an arylsulfatase deficient host*

*cell ... and (c) optionally recovering the polypeptide from the nutrient medium or from the host cell."*

11. Claim 29 of the application as filed contains no back reference to the process or the host cell of claim 26 of the application as filed. That the process of claim 29 uses in step (a) an arylsulfatase deficient host cell does not in itself provide for the skilled person any indication that inclusion of the production of the arylsulfatase deficient host cell in the process of claim 29 is envisaged in the application as filed.
12. The board therefore shares the view of the respondent that a requisite pointer to the specific combination of the subject-matter of claim 26 with that of claim 29 of the application as filed is missing in the claims.
13. On page 17, lines 25 to 33, the application as filed discloses a process to produce a host cell which is an arylsulfatase deficient strain. As noted by the respondent (reply, II.7), this process and the process to produce a polypeptide disclosed on page 17, line 34 to page 18, line 6 of the application as filed are disclosed as two separate embodiments which relate to independent aspects of the invention.
14. Therefore, a necessary pointer to the specific combination of the claimed features cannot be derived from page 17, lines 25 to 33 of the application as filed either and the opposition division's assertion regarding an alternative basis for step a. of the process of claim 1 of the main request on page 17, lines 25 to 33 of the application as filed is therefore not correct.

15. The appellant initially submitted that the text on page 17, lines 25 to 33 of the application as filed could be read together with the text on page 17, line 34 to page 18, line 6 because "[T]he arylsulfatase deficient host cell can be equated with the host cell which is arylsulfatase deficient in the preceding passage" (statement of grounds of appeal, page 4, penultimate paragraph in conjunction with page 7, third and fifth paragraph). It further argued that claims 26 and 29 of the application as filed could also be read together because the arylsulfatase deficient host cell of claim 29 'can be equated' with the host cell which is arylsulfatase deficient of claim 26 (ibid., page 6, sixth paragraph in conjunction with page 7, third to fifth paragraph).
16. The appellant's argument is thus similar to that of the opposition division (point 6. above) and it fails essentially for the same reasons (points 8. to 14. above).
17. At the oral proceedings before the board, the appellant put forward additional arguments in support of a basis for step a. of claim 1 in the application as filed. For the reasons set out below, none of these arguments are considered persuasive.
18. First, the appellant submitted that "*an arylsulfatase deficient host cell*" in step (a) of claim 29 of the application as filed acted as a pointer. The skilled person reading claim 29 of the application as filed would recognise that they had to provide "*an arylsulfatase deficient host cell*" and would turn to claim 26 of the application as filed because it provides a process "*to form the host cell which is arylsulfatase deficient*". Therefore, the appellant

argued, the skilled person would read the processes of claims 26 and 29 of the application as filed together. Thus, they could be combined without adding matter. The disclosure of a method for producing an arylsulfatase deficient organism on page 9 of the application as filed (see "2)") also served as a pointer to the combination of claims 26 and 29 of the application as filed.

19. However, in agreement with the respondent, the board considers that the reference to "*an arylsulfatase deficient host cell*" in step (a) of the process of claim 29 of the application as filed does not imply that any particular process is used to provide that host cell and, accordingly, does not imply that the process of claim 26 of the application as filed is used to provide "*an arylsulfatase deficient host cell*" in step (a) of the process of claim 29 of the application as filed, in particular when considering that the application as filed discloses various different methods for producing an arylsulfatase deficient host cell (see point 20. below). The requirement for "*an arylsulfatase deficient host cell*" in step (a) of the process of claim 29 of the application as filed therefore does not serve as an indication that the combination of claims 26 and 29 of the application as filed is envisaged in the application as filed.
  
20. The passage on page 9 of the application as filed on which the appellant relies, when read in context, discloses the following methods for providing an arylsulfatase deficient host "2) *elimination or disruption of the gene for aryl-sulfatase from the genome of the organism by either random mutagenesis techniques or by a directed approach using e.g. molecular biology technologies known to the person*

*skilled in the art, 3) screening and selection of a strain that is a natural low producer or non-producer of aryl-sulfatase activity;*" (page 9, lines 29 to 33 of the application as filed). In agreement with the respondent, the board considers that these methods are disclosed as equally preferred and therefore the methods of option 2) do not serve as an indication that the combination of claims 26 and 29 of the application as filed is envisaged in the application as filed. Furthermore, as also noted by the respondent, the methods of option 2) provide a knock-out organism and are therefore more specific than the process of claim 26 of the application as filed. Also for this reason, the appellant's argument based on page 9 of the application as filed fails.

21. As a second line of argument, the appellant submitted that basis for claim 1 of the main request was provided by the last sentence on page 17 of the application as filed. They argued that the expression "*further provides*" in this sentence indicated to the skilled person that the "*process to produce a polypeptide*" built on what had been described before, i.e. the "*process to produce a host cell which is an arylsulfatase deficient strain*" disclosed on page 17, lines 25 to 33, of the application as filed.
22. The last sentence on page 17 of the application as filed reads "[t]he invention further provides a process to produce a polypeptide ... " (page 17, line 34 of the application as filed). In agreement with the respondent, the board considers that this sentence indicates that the process to produce a polypeptide is a different aspect of the invention, not a further aspect of the process that has been described before, i.e. the "*process to produce a host cell which is an*

*arylsulfatase deficient strain*" disclosed on page 17, lines 25 to 33, of the application as filed (see also point 13. above). Therefore, the last sentence on page 17 of the application as filed does not provide any indication that the combination of the "*process to produce a polypeptide*" disclosed on page 17, line 34 to page 18, line 6 of the application as filed and the "*process to produce a host cell which is an arylsulfatase deficient strain*" disclosed on page 17, line 34 to page 18, line 6 of the application as filed is envisaged. Moreover, as also noted by the respondent, the phrase "[t]he invention further provides a process to produce a polypeptide..." is used in the application as filed in the context of four different processes for producing a polypeptide (see page 17, line 34; page 18, line 7; page 18, line 16 and page 18, line 23), and no preference for any of these different processes can be inferred from pages 17 and 18 of the application as filed. For that reason also, the appellant's argument based on the last sentence on page 17 of the application as filed fails.

23. In a third line of argument, the appellant submitted that the application as filed as a whole disclosed the use of mutagenesis or genetic manipulation techniques to reduce the aryl-sulfatase activity of a host strain and also to use that host strain to produce a lactase preparation (page 22, lines 18 to 25; Examples 14 and 15). That, they asserted, provided a clear pointer to the skilled person to combine claims 26 and 29 of the application as filed.
  
24. On page 22, lines 18 to 25, the application as filed discloses that "[s]uch industrial production strains with decreased arylsulfatase activity isolated or constructed by classical genetic techniques or

*recombinant DNA technology may be used for relevant industrial processes that require the final product to lack off flavour. Preferably these strains are used for the production of industrially relevant enzymes. More preferably these strains are used for the production of enzymes that are used in the food industry, even more preferably these enzymes are used in processing of dairy products. Most preferably such industrial production strains with decreased arylsulfatase activity are used for the production of lactase."*

25. Example 14 relates to the construction of an arylsulfatase knock-out strain of *Kluyveromyces lactis* (page 45, line 6 to page 50, line 17 of the application as filed) and Example 15 discloses that no arylsulfatase activity could be detected in the knock-out strain (page 50, lines 31 to 33). Example 15 concludes with the statement that "[t]he mutant strain can be used to make a lactase preparation at industrial scale, virtually devoid of arylsulfatase activity" (page 51, lines 3 and 4 of the application as filed).
26. The appellant has not provided any argument as to why the skilled person would directly and unambiguously infer from the explicit disclosure that a particular host strain can be used to produce a lactase preparation (see points 24. and 25. above) an implicit indication that, instead of the host strain, a process for its production is to be used as part of the process for producing a lactase preparation. In agreement with the respondent, the board further considers that the industrial production strains (see point 24. above) and the knock-out strain of *Kluyveromyces lactis* (see point 25. above) are in any case specific embodiments of arylsulfatase deficient host cells. The disclosure of

their use for the production of lactase therefore does not in any way indicate that the combination of claims 26 and 29 is envisaged in the application as filed. The appellant's third line of argument must therefore also be rejected.

27. The board concludes from the above considerations that the skilled person would not directly and unambiguously derive from the teaching of the application as filed as a whole a process for preparing a lactase preparation which includes as a step of that process the generation of the arylsulfatase deficient host cell as required by step a. of claim 1.
28. It is therefore not necessary to consider whether the remaining features of claim 1 find a basis in the application as filed.
29. The subject-matter of claim 1 extends beyond the content of the earlier application as filed. The ground of opposition under Article 100(c) EPC, added matter, therefore prejudices the maintenance of the patent as granted (main request).

*Auxiliary requests 1 to 4*

*Added subject-matter (Article 100(c) in conjunction with Article 76(1) EPC) - claim 1*

30. Claim 1 of auxiliary request 1 is identical to claim 1 of the main request. Claim 1 of each of auxiliary requests 2 to 4 is directed to a process to produce a lactase preparation that includes a step directed to the production of the arylsulfatase deficient host cell as in claim 1 of the main request (see section V. above).



31. The observations set out above for claim 1 of the main request therefore apply, *mutatis mutandis*, to claim 1 of each of auxiliary requests 1 to 4. This was not contested by the appellant.
32. Claim 1 of auxiliary requests 1 to 4 contravenes Article 76(1) EPC.

### *Conclusion*

33. The main request and auxiliary requests 1 to 4 are not allowable. In the absence of an allowable claim request the decision under appeal cannot be set aside and the appeal must be dismissed.

### **Order**

#### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

T. Sommerfeld

Decision electronically authenticated