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# Datasheet for the decision of 1 June 2022

Case Number: T 1822/19 - 3.3.09

Application Number: 07824430.8

Publication Number: 2094107

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Language of the proceedings: EN

Title of invention:

MYCOTOXIN-REDUCING COMPOSITION

Patent Proprietor:

Blue Ridge Solutions Ltd

Opponent:

DSM Austria GmbH

Headword:

Micotoxin detoxification/DSM

# Relevant legal provisions:

EPC Art. 56

# Keyword:

Main request and auxiliary requests 1 to 9: inventive step - (no)

#### Decisions cited:

T 0743/89, T 0804/05, T 2451/13, T 2253/14

#### Catchword:



# Beschwerdekammern Boards of Appeal

Chambres de recours

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Case Number: T 1822/19 - 3.3.09

DECISION
of Technical Board of Appeal 3.3.09
of 1 June 2022

Appellant: DSM Austria GmbH (Opponent) Erber Campus 1

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Representative: Cunow, Gerda

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Respondent: Blue Ridge Solutions Ltd

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Representative: Gill Jennings & Every LLP

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 15 April 2019 concerning maintenance of the European Patent No. 2094107 in amended form.

#### Composition of the Board:

Chairman A. Haderlein
Members: A. Veronese
N. Obrovski

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### Summary of Facts and Submissions

- I. The appeal was filed by the opponent (appellant) against the decision of the opposition division finding that the European patent as amended in accordance with the main request filed with the submissions dated 4 January 2019 met the requirements of the EPC. This claim request corresponds to the main request filed during the oral proceedings held before the board during the previous appeal proceedings T 2253/14, which related to the same case.
- II. Claim 1 of this main request reads as follows:
  - "1. A composition for reducing the toxicity of a trichothecene mycotoxin, comprising an enzyme, a mycotoxin-binding agent and a Saccharomyces yeast capable of taking up a trichothecene mycotoxin."
- III. With its notice of opposition, the opponent had requested that the patent be revoked in its entirety, inter alia on the grounds under Article 100(a) (lack of novelty and lack of inventive step) and 100(c) EPC.
- IV. In its earlier decision T 2253/14, the board found that the main request met the requirements of Article 123(2) and (3) EPC and was novel over the teaching of D1 and D9.
- V. The board remitted the case to the opposition division, which found, inter alia, that the subject-matter of that main request involved an inventive step over D9, considered as the closest prior art, alone or in combination with one or more of the other cited documents.

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- VI. The documents submitted during the opposition proceedings included:
  - D1: Leaflet from Biomin GmbH "Mycofix Plus always a step ahead in mycotoxin deactivation" (2004)
  - D2: D.S. Verma, Poultry line, August 2005, pp. 25-27
  - D4: G. Devegowda et al., Biotechnology in the Feed Industry, Proceedings of the Alltech's 14th Annual Symposium, 1998, pp. 241-255
  - D5: M. Magan et al., Mycotoxin in Food Detection and control, 2004, Section 9, pp. 190-223
  - D7: J.P. Jouany, Animal Feed Science and Technology, 9 June 2007, pp. 342-362
  - D9: WO 96/12414
  - D24: Nachdruck Mycofix Plus MTV Folder English
  - D25: Declaration of Ursula Hofstetter-Schäns, dated 25 June 2015
  - D28: Screenshot showing a photo taken in 2004
  - D31: Experimental report filed by the respondent with its submission dated 4 January 2019
  - D33: H. Bejaoui et al., Journal of Applied Microbiology, 2004, Vol. 97, pp. 1038-44
  - D34: Experimental report from Micro Bio-Systems Ltd on DON binding, filed by the respondent with its submission dated 4 January 2019
  - D36: I. Styriak et al., Mycotoxin Research, 2001, Vol. 17, Supp. 1, pp. 24-27
  - D40: Experimental report filed by the respondent with its reply to the statement setting out the grounds of appeal
  - D41: Experimental report filed by the respondent with its reply to the statement setting out the grounds of appeal

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- VII. During the present appeal proceedings, the proprietor (respondent) requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 and 3 filed with the submission dated 4 January 2019, or of auxiliary requests 5 to 9 filed with the submission dated 28 February 2019.
- VIII. Claim 1 of auxiliary requests 1, 3 and 5 to 9 differs from claim 1 of the main request in particular in that the yeast is Saccharomyces cerevisiae, in that the mycotoxin is deoxynivalenol, in that certain specific enzymes or enzyme combinations are selected, or in that certain specific binding agents are selected.
- IX. The appellant considered that the subject-matter of claim 1 of all the requests did not involve an inventive step, and submitted essentially the following:
  - D9, which disclosed the use of *Saccharomyces* extracts for reducing the toxicity of mycotoxin in foods was the closest prior art. D1 was part of the state of the art
  - the claimed composition differed from that of D9 in that it comprised live Saccharomyces yeast
  - the claimed composition was not compared with that of D9; furthermore, the tests in D31, D40 and D41 did not show synergism between the ingredients present in the claimed composition
  - since not all *Saccharomyces* yeasts metabolised trichothecene mycotoxins, the results of the tests could not be generalised
  - starting from D9, the underlying problem was the provision of an alternative composition

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- in view of D36, the skilled person would have considered including live *Saccharomyces* yeast in the compositions of D9; D1 and D2 showed that the skilled person would not have had a prejudice to include microorganisms like *Saccharomyces* in foods
- the features characterising the auxiliary requests did not induce any new technical effect and did not confer inventiveness on the claimed subject-matter.
- X. The **respondent** considered that the subject-matter of claim 1 involved an inventive step, and submitted essentially the following:
  - D9 was the closest prior art
  - D1 was not part of the state of the art
  - the prior art taught away from using live

    Saccharomyces yeasts; the results in D9, obtained using cell extracts, were insignificant
  - the prior art, e.g. D34, taught that binders did not absorb trichothecene mycotoxins; however, as shown in the patent, D31, D40 and D41, a combination of live *Saccharomyces* yeasts and binders induced a synergistic effect on trichothecene degradation
  - the claimed combination represented an improvement not just an alternative, to that of D9
  - the teaching of D36 was questionable and did not point towards the claimed solution
  - D2, D4, D5, D7 and D8 discouraged the use of live bacteria for detoxifying foods
  - were D1 considered to belong to the state of the art, the case would have to be remitted to the opposition division
  - these arguments applied to all the requests on file.

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#### Requests

- XI. The **appellant** requested that the decision under appeal be set aside and that the patent be revoked in its entirety.
- XII. The **respondent** requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of:
  - one of auxiliary requests 1 and 3 filed with the submission dated 4 January 2019 or, alternatively,
  - on the basis of one of auxiliary requests 5 to 9 filed with the submission dated 28 February 2019.

#### Reasons for the Decision

#### Main request

1. Inventive step

Closest prior art

- 1.1 The opposed patent relates to a composition reducing the toxicity of a trichothecene mycotoxin in a foodstuff. As explained in the section of the patent describing the background of the invention, mycotoxins are produced by fungi and can induce toxic effects in humans and animals. For example, they can contaminate agricultural products administered to animals, induce vomiting, cause higher mortality, reduce growth and decrease the production of milk.
- 1.2 When assessing inventive step, the opposition division decided that D9 was the closest prior art. The parties

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did not contest this, and the board does not see any reason to diverge from this choice either. Like the opposed patent, D9 relates to a composition for reducing the toxicity of mycotoxins, including trichothecene mycotoxins, in a foodstuff. The composition comprises an enzyme extract obtained from Saccharomyces strains or inactivated Saccharomyces strains comprising the enzymes, in combination with a porous binding agent.

## Distinguishing features

- 1.3 The respondent considered that the claimed subjectmatter differed from the teaching of D9 in terms of two features, namely in that the claimed composition:
  - contained Saccharomyces yeast capable of taking up a trichothecene mycotoxin, and
  - was suitable for reducing the toxicity of a trichothecene mycotoxin.
- 1.4 Drawing attention to the results in table 1 of D9, the respondent argued that this document did not actually show that the disclosed composition induced the purported detoxifying effect. In its opinion, the suitability of the composition for reducing trichothecene toxicity was thus a further technical feature distinguishing the subject-matter of claim 1 from the prior art in addition to the first one, already identified by the board of appeal in its earlier decision T 2253/14 (points 4.3.3 and 4.3.4 of the reasons).
- 1.5 The respondent drew attention to table 1 of D9 and compared the intake of feed contaminated by mycotoxins

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by the animals of groups 1 and 4, 2 and 5, and 3 and 6, respectively. In its view, these comparisons showed that the composition according to D9 was ineffective against mycotoxins.

- 1.6 This argument is not convincing. In fact, an improvement in the other parameters observed, namely daily weight growth and food conversion rate, is observed when comparing the same groups. This is particularly the case if the results observed in groups 7 and 8, which relate to animals which have not ingested mycotoxins, are also taken into account. Although, as noted by the respondent, the increase in the rate of growth is stronger when the concentration of trichothecene T-2 is low, the effect persists at higher concentrations. The overall picture of the results makes it credible that the composition of D9 protects from both aflatoxin and trichothecene T-2 toxicity, and that, as stated in D9, both the enzymes and the absorbents comprised in the tested compositions are responsible for this effect.
- 1.7 It is thus concluded that, as stated in the description and in the claims of D9, the disclosed composition is suitable for reducing the toxicity of trichothecene mycotoxins including e.g. deoxynivalenol (DON), see page 5, lines 9 to 30, page 7, lines 4 to 11 and 29 to 36, page 8, lines 4 to 21, and claim 7.
- 1.8 For these reasons, the <u>only</u> technical <u>feature</u> <u>distinguishing</u> claim 1 from the teaching of D9 is the use of <u>a live Saccharomyces</u> yeast capable of taking up a mycotoxin.

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#### Technical effect and underlying technical problem

- 1.9 The properties of the composition according to the present invention have not been compared with those of the compositions described in D9. In particular, no comparison has been made between the compositions of examples D to F of the patent and those of D9. During the proceedings, the respondent referred to the results of the tests described in the experimental reports D31, D40 and D41, to D34 and to example 5 of the patent. In its view, these showed that a combination of live Saccharomyces yeasts and binding agents induced an unexpected synergistic degradation of trichothecene mycotoxin. In particular, in its opinion, these documents showed that:
  - D31: the combination of a live Saccharomyces cerevisiae yeast R 404 with a bentonite mycotoxin-binding agent synergistically reduced the concentration of a trichothecene mycotoxin in the tested samples
  - D34: trichothecene mycotoxins did not bind to bentonite binders, i.e. to typical mycotoxin-binding agents
  - example 5, paragraphs [0060] and [0061] of the patent, and D40 and D41: trichothecene mycotoxins were taken up by live Saccharomyces cerevisiae yeast R 404 and converted into their metabolites, which were then released by the yeast and bound by a bentonite binding agent and subjected to further degradation.
- 1.10 The respondent stated that typical mycotoxin-binding agents, such as bentonite, actually did not bind to

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trichothecene mycotoxins, although they could bind to their metabolites. Because of these properties, they created a concentration gradient which facilitated the export of toxic metabolites formed in the yeast cells to the surrounding environment. The yeast viability and its ability to take up and metabolise more mycotoxins was thus preserved. This mechanism of action explained the synergistic effect observed in D31, see paragraphs [0060] and [0061] of the patent and page 11, paragraphs 5 to 8 and page 12, paragraphs 5 and 6 of the respondent's reply to the statement setting out the grounds of appeal.

- 1.11 Since these results could not be expected, the claimed composition represented an improvement over the prior art. The underlying problem was thus the provision of an improved composition for detoxifying trichothecene mycotoxins.
- 1.12 The board does not consider the respondent's arguments convincing.
- 1.13 First of all, the allegation that typical mycotoxin-binding agents such as bentonite do not bind to trichothecene mycotoxins is not persuasive. Bentonite binders are in fact preferred mycotoxin-binders according to paragraph [0030] of the patent. This finding already raises the question of whether the purported synergistic effect can be achieved using any mycotoxin-binding agent. Furthermore, considering the mechanism of action described in the patent and by the respondent, it is clear that the alleged synergistic effect can only be achieved using Saccharomyces yeasts which are capable of metabolising trichothecene mycotoxins and forming metabolites which are excreted and bound by a mycotoxin-binding agent.

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- 1.14 D36 provides evidence that not all Saccharomyces yeasts have these properties. Some strains of Saccharomyces cerevisiae are in fact not able to metabolise trichothecene mycotoxins: page 26, section "Results and discussion", and table 1 of D36 show that some Saccharomyces cerevisiae strains (L11 and 73) are able, but others (IS1/1, I3 and LF1/1) are not able, to metabolise the trichothecene mycotoxins nivalenol and deoxynivalenol (DON).
- 1.15 The respondent argued that the results in D36 were not conclusive. The trichothecene metabolites had not been isolated and characterised, and the observed decrease in nivalenol and deoxynivalenol might simply result from their precipitation out of solution.
- 1.16 This criticism of D36 is not well-founded. As noted by the appellant, had precipitation occurred it would have been observed in all the samples. Furthermore, the respondent's argument clashes with the explicit statement on page 26 of D36 that "some yeast strains show no degradation ability while the other strains were capable to degrade some mycotoxins". The fact that D36 does not mention a binding agent and its potential relevance for taking up mycotoxins is irrelevant. What matters is that D36 teaches that some Saccharomyces cerevisiae strains are not capable of metabolising mycotoxins.
- 1.17 In view of the findings in D36, it is not credible that the effects shown in the opposed patent and in D31, D40 and D41 can be obtained with all strains of Saccharomyces cerevisiae. In other words, it is not credible that the alleged synergistic effect can be obtained across the entire scope claimed and that the

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effects of the claimed composition go beyond those already described in D9. It is also noted that the tests shown in example 5 of the patent and in D31, D40 and D41 were all carried out using the same R 404 Saccharomyces strain.

1.18 For these reasons, as asserted by the appellant, the underlying problem is the provision of an alternative composition for reducing the toxicity of a trichothecene mycotoxin.

Obviousness of the claimed solution

- 1.19 When confronted with this problem, the skilled person would have taken into account the teaching of the aforementioned document D36. Like the opposed patent, D36 relates to the reduction of trichothecene mycotoxin toxicity in foodstuffs using compositions capable of degrading toxins: see introduction, results and discussion. As already mentioned above, D36 discloses some strains of Saccharomyces cerevisiae which are capable of degrading trichothecene mycotoxins. The use of probiotic products for detoxification is also provided for, see conclusions.
- 1.20 In view of this teaching, the skilled person would have considered including the active strains described in D36 in the compositions of D9. Combining agents having beneficial detoxification properties is an obvious step that the skilled person would have carried out when confronted with the underlying problem.
- 1.21 The respondent objected that D9 focuses on the use of deactivated yeast cells and yeast cell extracts, and does not provide any motivation to use live cells.

  Starting from D9, the skilled person would, at most,

have investigated the effect of pH changes and different binders. In its opinion, at the time when the invention was made it would have been unlikely for a skilled person to consider the use of live cells. The common belief was that micro-organisms adversely affected the quality of foods and that biological control of toxicity was not yet feasible. Few microorganisms had been identified for detoxification, and these were mostly bacteria, not yeasts. Mycotoxins could also be toxic to yeasts. The mainstay of food detoxification involved the use of enzymes and binding agents rather than live micro-organisms. In this context the respondent referred in particular to: D5, paragraphs 9.2.4, 9.7.2 and page 208, last two paragraphs; D2, pages 26 and 27; D4, pages 249 and 250; D7, page 353, first full paragraph; and D33.

1.22 The respondent's arguments are not convincing. First of all, as the respondent conceded, D9 does not teach against using live yeasts for detoxification. Furthermore, the available prior art documents show that when the invention was made the use of live microorganisms, including yeasts capable of bio-transforming mycotoxins - possibly combined with binding agents for detoxifying animal feeds, was well established and considered a breakthrough in biotechnology. Products comprising a combination of live yeasts, adsorbing agents and enzymes were on the market for this purpose: see the brochure D1 disclosing Mycofix® Plus, a combination of enzymes, live cells and adsorbing agents for decontaminating animal feed from mycotoxins, including trichothecenes, and D2, pages 25 to 27, in particular the conclusions. This means that at the filing date no prejudice deterred the skilled person from using live micro-

organisms in food products.

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- The respondent contended that D1 was not part of the state of the art. This is not convincing. D1 is a commercial brochure bearing the date 2004. It is generally accepted that brochures are normally not kept secret for long after printing (T 2451/13, T 804/05 and T 743/89). The appellant has also filed a sworn declaration from a witness stating that the brochure was presented at three public events before the relevant date (D25), a picture showing that it was shown to the public before that date (D28), and evidence that the brochure was reprinted in 2006 (D24). No reasons were provided as to why this evidence would not be credible. Thus D1 is considered state of the art.
- 1.24 For these reasons it is concluded that, as argued by the appellant, when confronted with the underlying technical problem, the skilled person would have considered including the active strains described in D36 in the compositions of D9. Therefore the subjectmatter of claim 1 lacks inventive step (Article 56 EPC).

#### Auxiliary requests 1, 3 and 5 to 9

- 2. Inventive step
- 2.1 Claim 1 of auxiliary requests 1, 3 and 5 to 9 differs from claim 1 of the main request in that the yeast is Saccharomyces cerevisiae, in that the mycotoxin is deoxynivalenol, in that certain specific enzymes or enzyme combinations are selected, or in that certain specific binding agents are selected, and in combinations of these features.

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- 2.2 The appellant stated that these additional features were included to "narrow the claims around the data presented in the application and in D31 and thus in line with the surprising technical effects demonstrated".
- 2.3 However, since, as already explained above, it is not credible that the purported "surprising technical effects" can be achieved across the entire scope claimed, namely using any strain of Saccharomyces cerevisiae, and no other evidence has been presented that the additional features are associated with a new technical effect, the reasoning and the conclusions presented when examining the main requests apply mutatis mutandis to all the auxiliary requests.
- 2.4 Accordingly, the subject-matter of claim 1 of these requests does not involve an inventive step either (Article 56 EPC).
- 3. Decision not to remit the case
- 3.1 The respondent requested that the case be remitted to the opposition division if D1 was considered to be part of the state of the art.
- 3.2 This request cannot be granted. Considering the late stage of the proceedings, the fact that the case had already been remitted once by the board and that the inventive-step objection based on D1 had already been raised during the two earlier proceedings before the opposition division, remittal would not be appropriate in the present case (Article 11 RPBA 2020).

# Order

# For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is revoked.

The Registrar:

The Chair:



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A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated