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Datasheet for the decision of 26 January 2018

Case Number: T 2253/14 - 3.3.09

Application Number: 07824430.8

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Language of the proceedings: EN

Title of invention:
MYCOTOXIN-REDUCING COMPOSITION

Patent Proprietor:
Blue Ridge Solutions Ltd

Opponent:
Erber Aktiengesellschaft

Headword:

Relevant legal provisions:
EPC Art. 54, 123(2), 123(3)
EPC R. 139

Keyword:

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T 0581/91

Catchword:

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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 2253/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 January 2018

Appellant: (Patent Proprietor)	Blue Ridge Solutions Ltd 24b Gringley Road Misterton Doncaster DN10 4AP (GB)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Respondent: (Opponent)	Erber Aktiengesellschaft Industriestrasse 21 3130 Herzogenburg (AT)
Representative:	Cunow, Gerda Cunow Patentanwalts KG Teschnergasse 33/1/3 1180 Wien (AT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 October 2014 revoking European patent No. 2094107 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman W. Sieber
Members: N. Perakis
E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor against the decision of the opposition division revoking European patent No. 2 094 107.

II. With its notice of opposition the opponent requested revocation of the patent in its entirety on the grounds under Articles 100(a) (lack of novelty and of inventive step), 100(b) and 100(c) EPC.

The documents submitted during the opposition proceedings included:

D1: Prospectus "Mycofix® Plus", www.biomin.net;

D9: WO 96/12414 A1;

D12: Trichothecenes/Chemical, Biological and Toxicological Aspects, Developments in Food Science 4, edited by Yoshio Ueno, Kodansha Ltd. and Elsevier, 1983, pp. 1-19;

D19: G. Avantaggiato *et al.*, "Recent advances on the use of adsorbent materials for detoxification of *Fusarium* mycotoxins", *Food Additives and Contaminants*, 2005, 22(4), pp. 379-388.

III. Claim 1 of the main request before the opposition division, the only request relevant for this decision, reads as follows (amendments over claim 1 as granted in bold):

"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 mycotoxin."

The opposition division acknowledged that the amendment to claim 1 of the main request fulfilled the requirements of Article 123(2) EPC. In particular with regard to the term "trichothecene", it accepted that the terms "trichothene/tricothene" disclosed in the application as filed contained spelling errors and allowed their correction to "trichothecene" under Rule 139 EPC. In this context reference was made to D12 and D19. However, the opposition division held that the subject-matter of claim 1 lacked novelty over D9. Furthermore, as it held that claim 1 of auxiliary request 1 did not comply with the requirements of Articles 84 and 123(2) EPC, it revoked the patent. The opposition division did not deal with the issue of sufficiency of disclosure.

IV. On 3 December 2014 the patent proprietor (in the following the appellant) filed notice of appeal against the opposition division's decision. The statement setting out the grounds of appeal was filed on 24 February 2015, accompanied by a main request (identical to the main request of the decision under appeal), two auxiliary requests and the following new document:

D20: J.A. Barnett, "A history of research on yeasts 13. Active transport and the uptake of various metabolites", *Yeast*, 2008, 25, pp. 689-731.

The appellant requested that the opposition division's decision be set aside and that the main request be held to meet the requirements of Article 54 EPC, or that the auxiliary requests be held to meet the requirements of

Articles 54 and 123 EPC. It also requested that the case be remitted to the opposition division for consideration of the issues of sufficiency of disclosure and inventive step.

V. With letter of 29 June 2015, the opponent (in the following the respondent) filed its observations on the appeal and the following document:

D21: R. Mitterbauer *et al.*, "*Saccharomyces cerevisae* and *Arabidopsis thaliana*: Useful model systems for the identification of molecular mechanisms involved in resistance of plants and toxins", *European Journal of Plant Pathology*, 2002, 108, pp. 699-703.

The respondent requested that (i) the appeal be dismissed, (ii) D20 not be admitted into the proceedings and (iii) the case be remitted to the opposition division for further prosecution if the board decided that one of the requests met the requirements of Articles 54 and 123 EPC.

VI. On 13 October 2017 the board issued a provisional opinion on the outstanding issues in preparation for the oral proceedings.

VII. With letter of 22 December 2017, the appellant submitted sets of claims corresponding to a main request and auxiliary requests 1 to 3, whereby the main request was still identical to the main request of the appealed decision (see point III above). It also filed the following documents and requested that they be admitted into the proceedings:

D30: Declaration of Dr Stephen Mann, dated 19 December 2017;

D31: Annex 1: Experimental report;

D32: M. Grenson *et al.*, Multiplicity of the Amino Acid Permeases in *Saccharomyces cerevisae*, *J.Bacteriol.*, 1970, pp. 770-777.

VIII. Oral proceedings were held before the board on 26 January 2018. During these proceedings the board questioned the clarity of the claims of the main request. Thereafter the appellant filed a new main request in which claims 1, 8 and 13 were amended to consistently refer to mycotoxin (amendments over the claims of the previous main request underlined):

Claim 1:
"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."

Claim 8:
"A method according to claim 7, wherein the trichothecene mycotoxin to be modified is dioxynivalenol (DON)."

Claim 13:
"A composition according to any of claims 1 to 6, for use in the treatment of a disease caused by a trichothecene mycotoxin".

IX. The relevant arguments put forward by the appellant in its written submissions and during the oral proceedings may be summarised as follows:

- The subject-matter of claim 1 of the main request fulfilled the requirements of Article 123(2) EPC because, contrary to the assertions of the respondent, the class of trichothecene mycotoxins had been disclosed in the application as filed. The opposition division had acknowledged that the term "tricothene mycotoxin" in the application as filed (page 11, lines 1-2) was an obvious error and had allowed its correction to trichothecene mycotoxin under Rule 139 EPC (the appealed decision, point 2 of the reasons). Not only had trichothecene mycotoxins been known in the art at the priority date of the patent in suit (see D12 and D19), but reference to them had also been made in the application as filed in view of the disclosure of the toxin Deoxynivalenol (DON), which is an example of a trichothecene mycotoxin and not an example of the wrongly cited class of "trichotene/trichothene mycotoxins" (page 1, lines 20 and 31; page 6, lines 32-33; page 11, line 2). Since DON had been disclosed only as an example of a trichothecene mycotoxin, the original application had disclosed the whole class of these mycotoxins. Thus claiming the whole class did not correspond to an intermediate generalisation.

- The subject-matter of claim 1 of the main request was novel over D9 at least because the claimed composition comprised a *Saccharomyces* yeast, the cells of which were alive and thus capable of taking up a trichothecene mycotoxin, i.e. capable of transporting it across the cell membrane into the yeast cells (patent in suit, paragraph [0033]; D30). This was not possible in D9 because the enzyme preparation comprised inactivated cells of a

Saccharomyces yeast (page 3, lines 6-16; page 4, lines 6-13). This was explained by Dr Mann in D30 and shown by the technical evidence of D31.

X. The relevant arguments put forward by the respondent in its written submissions and during the oral proceedings may be summarised as follows:

- The subject-matter of claim 1 did not fulfil the requirements of Article 123(2) EPC because there was no basis in the application as filed for the feature "trichothecene mycotoxin". Only trichothene mycotoxins were disclosed in the application as filed, and these were chemically different from trichothecenes. The correction of the terms "trichothene/tricothene" to "trichothecene" should not have been allowed by the opposition division. The case law of the boards of appeal required the application of stringent criteria (see T 581/91).

- The subject-matter of claim 1 lacked novelty in view of D9, which disclosed an enzyme preparation including an enzyme, a mycotoxin-binding agent and a *Saccharomyces* yeast capable of taking up a mycotoxin. It might well be that the cells of this micro-organism were inactivated in the enzyme preparation. This, however, did not mean that the cells were not capable of taking up a mycotoxin. The term "taking up" in claim 1, in the absence of any specific definition in the patent in suit, should be interpreted broadly and should encompass sticking/binding of the mycotoxin on the micro-organism cell membrane. This was what happened in the enzyme preparation of D9. Taking up by transportation of the mycotoxin across the cell membrane was not an option for the skilled reader

of D9, who was aware in the light of D21 that the cells of *Saccharomyces* yeast developed mechanisms which prevented mycotoxins from penetrating inside the cells. If the appellant had found a specific *Saccharomyces* yeast which allowed such specific transportation (uptake), no such specific yeast had been disclosed in the patent in suit.

XI. The appellant requested that the decision under appeal be set aside, that the claims of either the main request filed during the oral proceedings before the board or one of auxiliary requests 1 to 3 filed with letter dated 22 December 2017 be held to meet the requirements of Articles 123(2) and 54 EPC and that the case be remitted to the opposition division for further consideration.

XII. The respondent requested that the appeal be dismissed and that, if any of the requests were found to fulfil the requirements of Articles 123 and 54 EPC, the case be remitted to the opposition division for further consideration. It also requested that D20 not be admitted into the proceedings.

Reasons for the Decision

Main request

1. Admission

1.1 During the oral proceedings the board reiterated its objection that in claim 1 of the then pending main request the mycotoxin was narrowly defined, i.e. as a trichothecene mycotoxin, in the context of the intended use, whereas it was more generally defined, i.e. as a

mycotoxin, when it was to be taken up by a *Saccharomyces* yeast. A similar discrepancy was present in claim 13 as regards the treatment of a disease caused by a mycotoxin.

1.2 The appellant then filed a new main request in which the subject-matter of claims 1 and 13 was amended such that the term "mycotoxin" was replaced by the term "trichothecene mycotoxin" (see point VIII above). As suggested by the respondent, claim 8 too was amended accordingly.

1.3 The respondent did not raise any objection to the admission of the new main request into the appeal proceedings, and the board had no reasons not to admit it, in particular as the clarity objection against claim 13 only emerged during the discussion in the oral proceedings.

2. Article 123(2) EPC - amendments

2.1 The respondent's objection as to added matter was directed to the amendment of granted claim 1, namely the insertion of the intended use "for reducing the toxicity of a trichothecene mycotoxin". Thus, this objection is an objection under Article 123(2) EPC and not under Article 100(c), as originally argued by the respondent.

2.2 However, the limitation of the mycotoxin class to trichothecene mycotoxin clearly and unambiguously derives from the application as filed. Reference is made to page 11, lines 1-2, which discloses:

"The mycotoxin can be any mycotoxin. Preferred mycotoxins include ... , a tricothene such as Deoxynivalenol ...".

2.2.1 The board acknowledges that this passage discloses the term "tricothene" and not "trichothecene". However, as the opposition division correctly noted, the reference to "tricothene" is an obvious mistake because Deoxynivalenol, which in the cited passage is disclosed as an example of a tricothene mycotoxin, in fact belongs to the class of trichothecene mycotoxins. In this context, reference is made to D12 (page 8, table 1-1, and page 15, table 1-4), D19 (page 380, right column, line 8 from the bottom, and page 382, table I) and D21 (page 699, right column, lines 4-5 from the bottom). The board confirms that the correction offered by the appellant under Rule 139 EPC and accepted by the opposition division is indeed the only possibility available to the skilled person when considering common general knowledge. This is indeed in conformity with the stringent condition to be applied when examining the correction of an obvious error, as mentioned in T 581/91 (Reasons 3, penultimate paragraph), and not in contradiction with that decision as alleged by the respondent. In the present case the correction under Rule 139 EPC was allowed not on the balance of probabilities - the circumstances of which had been criticised in T 581/91 - but on a more rigorous standard, i.e. the obviousness of the correction in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction.

2.2.2 The respondent argued that, even if the correction offered by the appellant were accepted, this resulted in an intermediate generalisation because the

application as filed referred only to Deoxynivalenol. The board does not agree. The application as filed discloses Deoxynivalenol as an example of the wrongly cited class tricothene/trichothene mycotoxins (page 1, lines 20 and 31; page 6, lines 32-33; page 11, line 2). The error is clearly not limited to this example only, but relates to the class in general. Thus the amendment is not the result of an intermediate generalisation.

2.3 The intended use of the claimed composition directly and unambiguously derives from the application as filed. Reference is made to page 10, lines 8-9, which discloses that the composition seeks to reduce mycotoxin levels, and to page 10, line 33, which discloses that the method seeks to reduce mycotoxin toxicity. It is therefore obvious that in the context of the composition too, the reduction of mycotoxin toxicity is sought.

2.4 In conclusion, the subject-matter of claim 1 of the main request complies with the requirements of Article 123(2) EPC. The same applies *mutatis mutandis* to amended claims 8 and 13 of this request, against which the respondent did not raise any objection under Article 123(2) EPC.

3. Article 123(3) EPC - amendments

The subject-matter of the claims of the main request corresponds to a limitation of the subject-matter of the claims as granted and therefore complies with the requirements of Article 123(3) EPC.

4. Article 54 EPC - novelty

4.1 The respondent argued that the disclosure of D9 anticipated the subject-matter of claim 1 of the main request.

4.1.1 D9 discloses a composition for the deactivation of a mycotoxin, which comprises an enzyme preparation manufactured from an inactivated extract of *Saccharomyces* yeast (claims 1-3; page 4, lines 1-13; page 5, lines 9-20). Deactivation of a trichothecene mycotoxin is achieved when a specific *Saccharomyces* yeast is used, namely *Saccharomyces telluris* (page 5, lines 20-25).

4.1.2 The respondent argued that the inactivated cells of the yeast extract in the enzyme preparation of D9 obviously contained enzymes, since the yeast was defined therein as an enzyme-producing (micro)organism (claim 1). Furthermore, it argued that these cells operated as mycotoxin-binding agents and were capable of taking up a trichothecene mycotoxin, since D9 disclosed that they were able to adsorb and partially decompose trichothecene mycotoxins (page 3, lines 6-13).

The respondent argued that since the patent did not provide any definition of the term "taking up", this term should be given its broadest meaning, which ultimately encompassed the "adsorption" of a trichothecene mycotoxin on the cell membrane. The result of this adsorption was that the cell on the one hand took up the mycotoxin and on the other hand bound it and thus also functioned as a mycotoxin-binding agent.

4.2 The appellant did not challenge the respondent's position that the enzyme, the mycotoxin-binding agent and the *Saccharomyces* yeast were not necessarily present as three separate components in the composition of claim 1. However, it argued that the inactivated cells of the yeast extract in the enzyme preparation of D9 were not capable of taking up a trichothecene mycotoxin as required by claim 1. According to the appellant, this feature rendered the subject-matter of claim 1 novel over the disclosure of D9.

4.3 Thus the novelty issue boils down to whether the inactivated yeast cells of D9 are capable of taking up a trichothecene mycotoxin.

4.3.1 Although it is true that the patent does not contain any explicit definition of the term "taking up" in relation to a trichothecene mycotoxin, such a definition may be implicit in view of the skilled person's common general knowledge. D21, to which the respondent - in another context - made reference, discloses toxin uptake in yeast (page 699, abstract; page 700, left column, lines 14-15 from the bottom), which means that the term at issue was not invented by the appellant but existed and was used in this technical field. Furthermore, contrary to the respondent's allegations, the patent in suit does provide an explanation of what happens to a trichothecene mycotoxin when it contacts a cell of a *Saccharomyces* yeast and how it is "taken up" by it. Reference is made to paragraphs [0032] and [0033]:

[0032]
"The purpose of the microorganism is to take up mycotoxins ... Once taken up, the microorganism sequesters the toxin, which cannot then be taken up by

the host animal. The microorganism's endogenous enzymes may then breakdown the toxins, although this is not an absolute requirement".

[0033]
"The microorganism has the function of physically taking up the toxin to sequester it within the bacterial or yeast cell. In the case of one toxin at least (DON), the toxin is modified in the cell and analogues are released, which are then able to bind to the binders where further enzyme degradation can take place." (underlining added by the board)

Thus, on the basis of the disclosure of the patent in suit considered in its entirety, "taking up" a trichothecene mycotoxin means that the mycotoxin is transported across the cell membrane into the cell.

4.3.2 In order to explain the significance of this term and to further clarify the difference between the yeast cells of D9 and those of the claimed yeast on the basis of their capacity to take up trichothecene mycotoxins, the appellant stated that only some small uncharged molecules, such as oxygen and carbon dioxide, were able to diffuse easily across the cell membrane. Large/ complex molecules, such as those of a trichothecene mycotoxin, could be transported across the cell membrane and into the cell only when the cell was alive. Only in live, physiologically respiring yeast cells could such a "taking up" take place, following either a mechanism which uses an energy source, such as ATP, to achieve uptake against a gradient and therefore increase the intracellular concentration of the trichothecene mycotoxin or a mechanism which binds the mycotoxin to a membrane component or carrier for transportation into the cell. The fundamental principle

of these uptake mechanisms was that no large or polar molecules could be taken across a membrane against, or creating, a gradient unless the cell was alive, had its membrane intact and was capable of utilising the energy produced by its active metabolism. Inactivated or non-intact cells could not produce energy or binding proteins and therefore were incapable of producing a gradient across the membrane.

4.3.3 Contrary to the live cells of the claimed composition, D9 discloses that the cells of the extract in the enzyme composition were inactivated in a known manner to obtain the release of enzymes (page 4, lines 6-13). In D30, Dr Mann explained that it would have been necessary to disrupt the cell membrane in order to obtain the enzymes that were previously inside the cell. However, this disruption of the cell membrane would prevent the inactivated cell from rejuvenating and subsequently from taking up larger molecules. That is to say that such cells might be regarded as dead. Thus uptake of a trichothecene mycotoxin cannot occur in the inactivated yeast cells of D9, which are no longer metabolically active and are not capable of producing a gradient across the membrane. This was confirmed in the technical evidence of D31 (Annex 1), according to which the concentration of trichothecene does not decrease in the presence of a *Saccharomyces* yeast extract, but does decrease in the presence of a live *Saccharomyces* yeast, this effect being explained by its capability of taking up trichothecene mycotoxin.

4.3.4 As the *Saccharomyces* yeast of the claimed composition is capable of taking up a trichothecene mycotoxin, this composition is novel over the enzyme preparation of D9.

4.3.5 The respondent argued on the basis of D21 that the taking up of trichothecene mycotoxins was not possible because the cells developed defence mechanisms which did not allow it. The board does not agree. D21 does not disclose that the cells of *Saccharomyces cerevisae* do not take up mycotoxins. It simply discloses that amino acid alterations in specific genes could play a role in trichothecene resistance in plants (page 699, abstract, last four lines) and that resistance to a toxic compound can be achieved inter alia by reducing net uptake (page 700, left column, lines 14-16 from the bottom). Thus this argument of the respondent is rejected.

4.4 During the oral proceedings the respondent acknowledged that D1 did not disclose a *Saccharomyces* yeast and consequently that it was not relevant for the novelty of the subject-matter of claim 1 of the main request.

4.5 To conclude, the subject-matter of claim 1 of the main request satisfies the requirements of Article 54 EPC.

5. Other independent claims

The respondent did not raise any objection against the subject-matter of the other independent claims, namely claim 7 (a method claim), claim 11 (a product claim), claim 12 (a first medical use claim) and claim 13 (a second medical use claim). As the subject-matter of all these claims refers to the composition of claim 1, which as set out above is novel over D9, the subject-matter of these claims is also novel over this document.

6. Dependent claims

The subject-matter of dependent claims 2-6 and 8-10 corresponds to preferred embodiments of the subject-matter of independent claims 1 and 7, and thus for the reasons given for the subject-matter of the independent claims the subject-matter of the dependent claims too is novel over D9.

7. D20

As none of the parties relied on D20, the board did not consider it necessary to decide on its admission into the proceedings.

8. Remittal

In view of the request of both parties, the board decided to remit the case to the opposition division for further prosecution, in particular in order to assess sufficiency of disclosure and inventive step. The board notes that it is unusual to treat novelty before sufficiency, but accepts the order the opposition division has chosen to deal with the various objections raised in opposition, in particular since sufficiency of disclosure and inventive step appear to be linked in the present case.

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 claims 1 to 13 filed as main request during the oral proceedings before the board.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated