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Datasheet for the decision of 27 January 2026

Case Number: T 1096/24 - 3.3.09

Application Number: 16725437.4

Publication Number: 3298404

IPC: A23L33/00, A23C9/20, G01N33/53

Language of the proceedings: EN

Title of invention:
KIT-OF-PARTS TO IDENTIFY MOTHER'S MILK MISSING FUCOSYLTRANSFERASE-2 DEPENDENT GLYCANS

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:
Nestle/Kit-of-Parts

Relevant legal provisions:
EPC Art. 123(2), 113(1)
EPC R. 103(1)(a)

Keyword:

Amendments - allowable (no) - Unallowable intermediate generalisation
Right to be heard - substantial procedural violation (no)

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Case Number: T 1096/24 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 27 January 2026

Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 June 2024 concerning maintenance of the European Patent No. 3298404 in amended form.**

Composition of the Board:

Chairman	A. Veronese
Members:	S. Arrojo
	G. Decker

Summary of Facts and Submissions

I. The appeal from the opponent is directed against the decision of the opposition division to maintain European patent No. 3 298 404 in amended form on the basis of auxiliary request 8 as filed on 25 April 2024.

II. The opponent (appellant) requested that the above decision be set aside and that the patent be revoked. The appellant also requested reimbursement of the appeal fee, alleging a violation of its right to be heard.

The appellant argued that claim 1 according to the request held allowable by the opposition division did not meet the requirements of Articles 83, 84 and 123(2) EPC and that the subject-matter of claim 1 was not inventive starting from D3 as the closest prior art in combination with D2, D7, D11, D12, D14, D22 and D24.

III. In the reply to the appeal, the patent proprietor (respondent) requested that the appeal be dismissed and that the patent be maintained in amended form on the basis of the claims upheld by the opposition division (main request, corresponding to auxiliary request 8 found allowable by the opposition division). Alternatively, the respondent requested that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 1 to 3 (identical to auxiliary requests 9 to 11 as filed on 24 April 2024).

IV. Claim 1 according to the **main request** reads as follows:

"1. Diagnostic kit comprising a matrix made of silica to identify in vitro mother's milk missing fucosyltransferase-2 (FUT2) dependent glycans comprising a line of a plant lectin from Ulex europaeus suitable to bind 2'fucosyl-glycans and a line of a positive control to bind a mother's milk protein, both labelled with different dyes, and

a device suitable to receive such a matrix provided with a milk application window and a read-out window,

wherein said positive control comprises an antibody specific for a specific milk protein, and

wherein the lectin and the antibody will migrate with the milk when the milk applied to the milk application window reaches the lines of the lectin and the antibody specific for a specific milk protein."

- Claim 1 according to **auxiliary request 1** defines a kit-of-parts comprising a diagnostic kit as defined in claim 1 of the main request and one or more feeding doses of 2'fucosyl-glycans such as of 100 to 5 000 mg.

- The subject-matter of claim 1 according to **auxiliary request 2** corresponds to that of the main request, where the claim specifies that "*the application of a milk sample to the milk application window will lead to migration of small milk components*".

- Claim 1 according to **auxiliary request 3** defines a kit-of-parts comprising a diagnostic kit as defined in

claim 1 of auxiliary request 2 and one or more feeding doses of 2'fucosyl-glycans such as of 100 to 5 000 mg.

V. In a communication under Article 15(1) RPBA dated 24 September 2025, the board expressed its preliminary opinion that none of the claim requests submitted by the respondent appeared to meet the requirements of Article 123(2) EPC and that, consequently, the patent would likely be revoked.

VI. In a submission dated 2 October 2025, the proprietor-respondent withdrew its request for oral proceedings.

VII. In a submission dated 15 October 2025, the opponent-appellant also withdrew its request for oral proceedings.

Reasons for the Decision

Main request

1. Decision in writing

Since all the parties withdrew their requests for oral proceedings and made no substantive submissions to the board's communication under Article 15(1) RPBA, the board is in a position to issue a written decision confirming its preliminary opinion.

2. Article 123(2) EPC

2.1 The appellant contended, *inter alia*, that there was no basis in the application as filed for incorporating the following features into the subject-matter of claim 1:

"*wherein the lectin and the antibody will migrate with the milk when the milk applied to the milk application window reaches the lines of the lectin and the antibody or fragment thereof specific for a specific milk protein*"

2.2 The respondent submitted that the incorporation of the above features into claim 1 was supported by the passage on page 8, lines 10 to 16, of the description as filed.

2.3 The appellant argued that the cited passage referred to a method rather than to a product and that even if the method features were considered an allowable functional definition of the product, several features disclosed in the passage on page 8 had been omitted from claim 1, resulting in an unallowable intermediate generalisation. More specifically (see point 2.2 of the statement of grounds of appeal), the following functional features had been omitted from claim 1, despite being presented as an essential part of the method defined on page 8, lines 10 to 21:

i) the migration of the small milk components such as fucosylglycans with the milk

ii) the slower migration of the bound lectins and antibodies

iii) the substrate-bound lectin and antibody reaching the height of the read-out window

iv) the determination of the result

The appellant further argued (see point 2.2.1 of the statement of grounds of appeal) that by omitting these features, the subject-matter of claim 1 had been broadened to cover embodiments that would not fulfil the functional requirements inherent to the first embodiment described on page 8 of the application as filed. In particular, the claim now encompassed embodiments in which the fucosylglycans did not migrate, or at least not at a lower speed than the unconjugated lectin, and/or in which the two bands required for a positive result did not appear within the read-out window. It could therefore not be concluded, as the opposition division had done, that the subject-matter of claim 1 necessarily retained the same functional limitations as the embodiment disclosed on page 8, lines 10 to 21 of the application as filed.

Accordingly, the appellant submitted that claim 1 constituted an unallowable intermediate generalisation of that embodiment.

2.4 The respondent submitted (see point 3.2 of the reply) that there was no reason to conclude that the features defined in the various sentences on page 8, lines 10 to 21, were inextricably linked. It was therefore not necessary to incorporate each of these sentences into claim 1 to define its subject-matter. Moreover, since the claim was directed to a product, the omission of some of the steps described on page 8 was allowable under Article 123(2) EPC, as they merely explained how the invention operated and had no limiting effect on the subject-matter of the product claim 1.

2.5 The board has concluded that the subject-matter of claim 1 extends beyond the content of the application as filed for the following reasons.

2.5.1 The features defining how the kit is used and how it works in the passage on page 8, lines 10 to 21, impose additional structural limitations on the kit defined in the preceding passage, because that kit must be configured to be suitable to carry out the diagnostic method which is the object of the invention. This was also the approach adopted by the opposition division when construing the contested feature "*wherein the lectin and the antibody will migrate [...]*"(see point 14.4.2 of the decision under appeal), which the opposition division interpreted as requiring that the product be configured such that the lectin and the antibody are not immobilised within the matrix, at least when in contact with the mother's milk.

2.5.2 As argued by the appellant, the apparatus must be configured in a specific manner to achieve the functions described in this passage — namely, by selecting an appropriate lectin and antibody, and by arranging the matrix, the application window and the read-out window so that, in the event of a positive signal, two bands simultaneously reach and become visible through the read-out window. This understanding is consistent with the submissions of the respondent, which, on page 19 of its reply, provided a detailed explanation of the embodiment in question, accompanied by an illustrative representation showing how the diagnostic method of the invention is to be carried out, how it works and how the kit must be configured.

2.5.3 The board also agrees with the appellant that at least some of the configuration requirements derivable from the passage on page 8, lines 10 to 21, are neither implicit from the wording of claim 1 nor merely optional features. In particular, the passage in

question specifies how the diagnostic kit of the invention is to be used and how it works to identify milk missing FUT2 and distinguish positive from negative results. Each sentence of this passage contributes to defining how the kit is used and functions and, implicitly, its structural requirements. Consequently, none of those sentences can be used in isolation as a basis for an amendment, let alone for further characterising the diagnostic kit described in the preceding passage on page 8, lines 1 to 8, as filed. Doing this creates subject-matter which extends beyond the content of the application as filed.

2.5.4 A comparison between the scope of the first embodiment disclosed on page 8, lines 1 to 8, and that of claim 1 at issue best illustrates this point.

Reference is first made to page 19 of the respondent's reply, which, as noted above, explains and illustrates, by means of several figures, the use, functioning and configuration of the diagnostic kit of the invention in accordance with the teaching of page 8, lines 1 to 21, as originally filed. According to this configuration, the lectin forms a complex with the fucosylglycans which migrates more slowly than the uncomplexed lectin, thus enabling the distinction between a positive and a negative result. A positive reading requires that the migrating speed of the complex formed by the milk protein and the antibody is such that both complexes reach the read-out window simultaneously, thereby providing the signal in the form of two visible bands. Conversely, a negative signal is observed as a result of the faster migration of the uncomplexed lectin, which leads to the appearance of a single band visible through the read-out window.

By contrast, the diagnostic kit of claim 1 is simply configured so that the lectin and the antibody migrate with the milk, i.e. that they are not immobilised. Thus, claim 1 at issue effectively covers any possible kit configuration containing a non-immobilised lectin and antibodies. Claim 1 does therefore not only cover a kit configuration as defined on page 8 as filed, but also other kit configurations comprising non-immobilised lectin and antibody which are suitable for identifying milk lacking FUT2. Such configurations may rely on other factors for distinguishing positive from negative results, including the colour of a single band, the specific time required by each band to reach the read-out window or alternative arrangements falling within the wording of the claims, such as sensors transmitting the signal to a digital read-out window.

The embodiment disclosed on page 8 does not provide a basis for such a broad interpretation as it is clearly limited to a particular kit configuration that enables the distinction between positive and negative results on the basis of the two-band identification described above. The subject-matter of claim 1 is therefore supported neither by this embodiment nor the broader scope of the claims as filed.

2.6 The requirements of Article 123(2) EPC are thus not met.

Auxiliary request 1

3. Article 123(2) EPC

3.1 Claim 1 according to **auxiliary request 1** defines a "kit-of-parts", rather than a diagnostic kit, as is the case in claim 1 according to the main request. However, this kit-of-parts comprises a diagnostic kit including the contested feature "*wherein the lectin and the antibody will migrate [...]*".

3.2 Since claim 1 still omits the above discussed features characterising the embodiment on page 8 of the description as filed, the objections raised against the main request also apply to claim 1 of auxiliary request 1.

3.3 This request therefore does not meet the requirements of Article 123(2) EPC.

Auxiliary requests 2 and 3

4. Article 123(2) EPC

4.1 Claim 1 of **auxiliary requests 2 and 3** respectively defines a diagnostic kit (as in the main request) and a kit-of-parts comprising a diagnostic kit (as in auxiliary request 1) but now specifies that the small milk components migrate when the milk sample is applied to the milk application window.

4.2 While this addresses part of objections raised by the appellant against the main request (see point 2.3 i) above), claim 1 still omits the other functional features which, according to the teaching of page 8 as

filed, are required to produce positive and negative read-outs.

4.3 In particular, the subject-matter of claim 1 according to these requests still covers diagnostic kits in which the distinction between the positive and the negative results is not based on the two-band principle but instead relies on other factors and/or configurations (see, for example, those mentioned in point 2.5.4 above).

4.4 The amendments to claim 1 do therefore not overcome the outstanding objections, so auxiliary requests 2 and 3 do not meet the requirements of Article 123(2) EPC.

5. Alleged substantial procedural violation

5.1 The appellant requested that the appeal fee be reimbursed pursuant to Rule 103(1)(a) EPC, arguing that the opposition division had failed to address its objections against claim 5 of auxiliary request 8 (held allowable by the opposition division) concerning sufficiency of disclosure.

5.2 The appellant submitted that this objection had been raised in point 5.2 of the notice of opposition with respect to claim 10 as granted, which allegedly corresponded to claim 5 of auxiliary request 8 considered allowable by the opposition division. By not addressing this objection, the opposition division had violated the appellant's right to be heard (Article 113(1) EPC).

5.3 The board cannot accept the appellant's argument as the objection under Article 83 EPC was never raised against

claim 5 of the auxiliary request held allowable by the opposition division. Furthermore, there is no basis for concluding that the objections raised against claim 10 as granted are implicitly applicable to claim 5 of the request held allowable by the opposition division.

5.3.1 More specifically, the board has found no indication in the written submissions or the minutes of the oral proceedings that an objection of insufficiency of disclosure was raised and/or discussed for claim 5 of auxiliary request 8.

5.3.2 There is likewise no basis for concluding that the opposition division should have recognised that the objections raised against granted claim 10 would also apply to claim 5 of the auxiliary request at issue. Although the subject-matter of granted claim 10 is similar to that of claim 5 of the request held allowable by the opposition division, the claims are not identical. In particular, claim 5 is a use claim that refers back to a kit-of-parts, which itself refers to diagnostic kits that differ from those defined in the granted claims. Specifically, use claim 10 as granted refers back to the diagnostic kit defined in granted claims 6 or 7, whereas claim 5 of the auxiliary request at issue refers back to the diagnostic kit defined in claims 1 or 2 of the request upheld by the opposition division, which differs from the former in several respects.

5.4 The board therefore concludes that in not addressing the question of sufficiency of disclosure for claim 5 of the request held allowable in the decision under appeal, the opposition division did not commit a substantial procedural violation.

5.5 Consequently, the appeal fee is not to be reimbursed.

6. Conclusions and further remarks

6.1 Since none of the requests submitted by the respondent meets the requirements of Article 123(2) EPC, the patent must be revoked.

6.2 In light of this conclusion, it is not necessary to address the additional objections under Articles 83, 84 and 56 EPC raised by the appellant.

6.3 Since documents D28 and D29 have not been relied upon in the current reasoning, there is likewise no need to examine the question of their admittance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

3. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

K. Götz-Wein A. Veronese

Decision electronically authenticated