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Datasheet for the decision of 25 April 2022

Case Number: T 2152/18 - 3.3.09

Application Number: 12723757.6

Publication Number: 2846648

IPC: A23L33/00, C13K5/00, A23L33/10

Language of the proceedings: EN

Title of invention:
INFANT FORMULAE AND THEIR PREPARATIONS

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Infant formulae/NUTRICIA

Relevant legal provisions:
EPC Art. 116, 100(b), 111(1)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)
Remittal - (yes)

Decisions cited:
T 0225/93, T 0749/98, T 0464/05, T 0431/07, T 0593/09, T 1772/09, T 2403/11

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Case Number: T 2152/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 25 April 2022

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	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:	**Decision of the Opposition Division of the European Patent Office posted on 9 July 2018 revoking European patent No. 2846648 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the patent proprietor's (appellant's) appeal against the opposition division's decision to revoke European patent No. 2 846 648.

II. In the notice of opposition, the opponent had requested that the patent be revoked based on, *inter alia*, Article 100(b) EPC.

III. In the decision under appeal, the opposition division revoked the patent. None of the requests met the requirement set out in Article 83 EPC.

IV. With the statement setting out the grounds of appeal, the appellant filed auxiliary requests 1 to 13.

V. By letter dated 17 July 2019, the appellant filed four further auxiliary requests (1A, 2A, 4A and 5A) in reply to objections from the opponent (respondent) under Article 123(2) EPC and changed its requests:

- auxiliary request 1 filed with the statement setting out the grounds of appeal became the main request
- auxiliary requests 2 to 13 filed with the statement setting out the grounds of appeal were renumbered to auxiliary requests 1 to 12
- in agreement with the respondent, remittal to the opposition division for discussion of novelty and inventive step was requested

VI. The respondent requested that the appeal be dismissed, otherwise that the case be remitted to the opposition division for discussion of novelty and inventive step.

VII. The board summoned the parties to oral proceedings. In a communication under Article 15(1) RPBA, it set out its preliminary opinion that for the main request the requirement set out in Article 83 EPC appeared to be complied with and that it intended to remit the case.

VIII. In reply to the communication, the respondent withdrew the request for oral proceedings. The appellant also concurred with the board's proposed remittal of the case.

IX. The board decided to cancel the oral proceedings and issue the present decision.

X. The documents referred to in this decision are:

D7: Product Specification: Lactochem® Microfine Issue date: 01 Jan 2016

D21: R. C. Rowe (co-editor), "Handbook of Pharmaceutical Excipients", 6th edn., London: Pharmaceutical Press, 2009, 359-369

XI. For this decision, only claim 1 of the main request is relevant. It reads:

"An infant formula powder composition comprising micronized lactose or lactose microcrystals (i) of which at least 80 % has a size less than 10 micrometer, and/or (ii) having a median particle size D50 below 10 micrometer."

Reasons for the Decision

1. *The patent*

The patent concerns infant formula powder compositions. The aim is to improve their flowing properties and reduce issues with caking or lumping. This is achieved by adding micronised lactose or lactose microcrystals to the compositions (paragraphs [0006] and [0008]).

2. *Main request - amendment*

Claim 1 of the main request is based on claim 1 of the application as filed, with one alternative option being deleted. There was no objection that this amendment adds subject-matter. Nor can the board see any issue under Article 123(2) EPC.

3. *Sufficiency of disclosure*

3.1 The opposition division decided that the invention lacked sufficiency of disclosure. The reason for this was the ambiguous definition of the particle size in all claim requests. This is the decision under review.

3.2 The patent in suit describes in paragraph [0031] how to provide the micronised lactose or lactose microcrystals useful in the invention. For example, lactose microcrystals may be milled or sieved to the desired particle size distribution. Lactose with a suitable particle size (e.g. Lactochem® Microfine) may also be purchased, as set out in paragraphs [0031] and [0048]. D7 and D21 confirm that such a commercial product, and

its typical particle size distribution, would have been known to the skilled person.

3.3 Thus, the skilled person would have been able to provide micronised lactose or lactose microcrystals with a small particle size distribution.

3.4 Whether such a distribution is within claim 1 is a question which concerns the matter for which protection is sought. It is an issue of clarity (Article 84 EPC).

3.5 The respondent provided elaborate arguments that different measurement methods, including a possible pre-treatment of the sample, would lead to different results, possibly within or outside of claim 1. It added that

"*in the absence of any indication in the opposed patent about how the 'size' of the lactose particles should be measured, the skilled person trying to reproduce the claimed invention has no knowledge about whether he has - or has not - solved the problem of improving the flow properties*" (reply to the statement setting out the grounds of appeal, page 10).

3.6 The board is not convinced that any ambiguity as to the particle size distribution would prevent the skilled person from carrying out the invention, i.e. adding micronised lactose or lactose microcrystals to improve the flow properties of an infant formula powder composition.

3.7 The patent's example section discloses a test protocol for assessing the flowability of an infant formula powder composition (paragraph [0048] and following). The test protocol can in theory be run with micronised

lactose or lactose microcrystals of any desired particle size. The results of such a test run are then assessed.

3.8 The board fails to see that carrying out the instructions of the test protocol would have placed an undue burden on the skilled person.

3.9 Thus, the skilled person would have been able to carry out the invention on the basis of the information in the patent and what was available to them at the effective date. This is the only criterion to be evaluated to decide whether the requirement of Article 83 EPC is met. Moreover, the skilled person would have been able to determine whether they had solved the problem of improving the flow properties.

3.10 The respondent cited several decisions. None of these are relevant to the case at hand.

3.10.1 In T 593/09 and T 2403/11, the underlying situation is different.

In those decisions, the claims called for a parameter range (T 593/09: "low temperature crystallization temperature ranging from 130 to 165°C"; T 2403/11: "a viscosity of 80-110 Pa.s at a temperature of 20°C"). In both cases, there was an explicit disclosure in the patent that working outside the range (i.e. above or below it) would not achieve the objective of the invention (i.e. solve the problem).

These decisions do not support the respondent's case, at least because in the patent in suit there is no such explicit disclosure of when the objective of the invention is not reached. Moreover, whether the problem

is solved does not solely depend on particle size distribution. It is assessed using the above-mentioned test protocol.

3.10.2 In T 1772/09, the claim under examination was directed to a crystalline form of aripiprazole (hydrate A), characterised by parameters (among others, an x-ray diffraction spectrum) and a mean particle size of 50 µm or less. The competent board held that the patent lacked relevant information for determining the particle size and the parameters, e.g. the operating conditions and the data analysis method for the diffraction instrument. It then concluded that the skilled person would not have had sufficient information to correlate a mean particle size measured for any given batch of aripiprazole hydrate A with the intended parameter.

The current case is different. Among other things, it is not necessary to correlate different parameters for reproducing the invention. Instead, claim 1 discloses a specified particle size distribution ("at least 80% has a size less than 10 micrometer"; "having a median particle size D50 below 10 micrometer"). The component called for in claim 1 is an ingredient commonly used in infant formula powder: micronised lactose or lactose microcrystals. As explained above, a useful product is commercially available, and its particle size distribution would have been known to the skilled person (e.g. from D21).

3.10.3 In T 464/05, the competent board held that "*the skilled person must be able to determine whether a particular object falls within the forbidden area of the claims intended as the area including those embodiments that*

effectively solve the technical problem underlying the patent in suit" (Reasons for the decision, point 3.5).

In this respect, the issues underlying decisions T 225/93, T 749/98 and T 431/07, to which the respondent referred, are similar.

However, this board agrees that "*today there is a clearly predominant opinion among the boards that the definition of the 'forbidden area' of a claim should not be considered as a matter related to Art. 83 and 100(b) EPC*" (Case Law of the Boards of Appeal of the EPO, 9th edition 2019, Chapter II.C.6.6.4).

3.11 Therefore, it can be concluded that the invention as claimed in the main request (originally filed as auxiliary request 1 with the statement setting out the grounds of appeal) complies with the requirement set out in Article 83 EPC.

4. *Remittal*

4.1 The opposition division did not examine the grounds for opposition under Article 100(a) EPC.

4.2 The case is remitted to the opposition division for further prosecution (Article 111(1) EPC).

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.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated