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**Datasheet for the decision
of 5 July 2022**

Case Number: T 2827/19 - 3.3.07

Application Number: 04798927.2

Publication Number: 1689360

IPC: A61K9/00

Language of the proceedings: EN

Title of invention:

DRY POWDER FORMULATIONS

Patent Proprietor:

Jagotec AG

Opponent:

Norton Healthcare Ltd

Headword:

Dry powder formulations/JAGOTEC

Relevant legal provisions:

RPBA Art. 12(4)

RPBA 2020 Art. 25(1), 25(2), 13(2)

EPC Art. 84

Keyword:

Admittance of late-filed request - main request (no)
Admittance of requests - auxiliary requests 1-6 (yes)
Admittance of an objection - admitted (yes)
Clarity - product-by-process claims - auxiliary requests 1-6
(no)

Decisions cited:

T 0123/85, G 0002/12, G 0002/13, T 0956/04, T 0768/08,
T 0150/12, T 0967/10, T 1988/12



Beschwerdekammern

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Case Number: T 2827/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 July 2022

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 2 August 2019
revoking European patent No. 1689360 pursuant to
Article 101(3)(b) EPC.**

Composition of the Board:

Chairman E. Duval
Members: J. Lécaillon
L. Basterreix

Summary of Facts and Submissions

I. European patent 1 689 360 (hereinafter "the patent") was granted on the basis of 9 claims. The independent claims of the patent as granted read as follows:

"1. A dry powder for inhalation comprising active particles and carrier particles for supporting active particles, the formulation further containing magnesium stearate in an amount of at least 0.5% by weight of the formulation, and wherein particles of magnesium stearate are disposed on the surface of the carrier particles such that the surface coverage of carrier particles, as determined using SEM-EDX, is less than 5%."

"7. A method of making the dry powder for inhalation as claimed in any one of claims 1 to 6 comprising the step of blending magnesium stearate with a carrier material in a low energy diffusion blender, wherein the energy consumption of said blender is from 0.1 to 1 kilowatt per 100 litres, for a period of less than 30 minutes."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as originally filed.

III. The opposition division took the decision to revoke the patent.

IV. The opposition division found that neither the main request, *i.e.* the patent as granted, nor any of the

auxiliary requests 1-5 met the requirements of inventive step.

- V. The patent proprietor (appellant) lodged an appeal against the above decision of the opposition division. With its statement setting out the grounds of appeal the appellant defended its case on the basis of an amended main request, and alternatively on the basis of auxiliary requests 1-2 filed therewith. The main request and the auxiliary requests 1-2 corresponded to auxiliary requests 3 and 4-5 filed in first instance proceedings on 16 October 2018 and 3 May 2019, respectively.
- VI. On 12 July 2021 the parties were summoned to oral proceedings.
- VII. With the letter dated 19 October 2021 the opponent (respondent) withdrew its request for oral proceedings and stated that it would not attend oral proceedings.
- VIII. With a communication dated 9 February 2022, the Board provided its preliminary opinion to the parties.
- IX. With letter dated 8 April 2022 the appellant submitted a new main request and three auxiliary requests 1-3. The previous requests became auxiliary requests 4-6.
- X. The content of the claims upon which the present decision is based can be illustrated as follows:

The new main request contained 7 claims, which corresponded to independent claim 1 and dependent claims 2 to 6 and 9 as granted.

Claims 1 of auxiliary requests 1 and 4 were identical and read as follows:

"1. A dry powder for inhalation comprising active particles and carrier particles for supporting active particles, the formulation further containing magnesium stearate in an amount of at least 0.5% by weight of the formulation, wherein the powder is obtainable by blending magnesium stearate with the carrier in a low energy diffusion blender, and wherein the energy consumption of said blender is from 0.1 to 1 kilowatt per 100 litres, for a period of less than 30 minutes."

Claims 1 of auxiliary requests 2 and 5 were identical and corresponded to claims 1 of auxiliary requests 1 and 4 wherein the following feature was added at the end of the claim:

"and wherein particles of magnesium stearate are disposed on the surface of the carrier particles such that the surface coverage of carrier particles, as determined by SEM-EDX, is less than 5%."

Claims 1 of auxiliary requests 3 and 6 were identical and corresponded to claims 1 of auxiliary requests 2 and 5 wherein the method for the determination of the surface coverage of carrier particles was amended to "SEM-EDX and BSE" (emphasis added).

XI. Oral proceedings were held before the Board on 5 July 2022.

XII. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or one of the auxiliary requests 1-3 filed on 8 April 2022, or one of the auxiliary

requests 4-6 filed with the statement setting out the grounds of appeal on 5 December 2019 as the main request and auxiliary requests 1-2.

The appellant also requested that the objection of lack of clarity in relation with product-by-process claims raised by the respondent not be admitted into the appeal proceedings.

XIII. The respondent requested that the appeal be dismissed and the patent be revoked.

XIV. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) The main request, which was based on granted claims, was to be admitted in the appeal proceedings in accordance with T 123/85. The main request had furthermore been filed in reply to the preliminary opinion of the Board and it did not significantly alter the arguments provided in the appeal proceedings.

(b) The auxiliary requests 1 to 6 were to be admitted in the appeal proceedings.

(c) The objection of lack of clarity in relation to product-by-process claims raised by the respondent should not be admitted, because it had been late-filed in opposition proceedings. Furthermore it contradicted the previous submissions of the respondent regarding the definition by means of a parameter.

(d) The requirements of Article 84 EPC were fulfilled by the product-by-process claims. The product-by-

process feature had been introduced in response to the objection of the respondent regarding sufficiency of disclosure in relation with the definition by a parameter. The introduction of this feature was meant to give clear guidance on the scope of the claims. Finally no lack of clarity arose from the feature of the energy consumption whose role was defined in the description.

XV. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

- (a) The auxiliary requests filed with the statement setting out the grounds of appeal (*i.e.* present auxiliary requests 5 and 6) were not to be taken into account as the appellant had not provided any substantiation for their admissibility or allowability.

- (b) The claims formulated as product by process claims did not meet the requirements of Article 84 EPC, since the claimed product could be defined by a testable parameter. Furthermore it was unclear how the energy consumption of the blender could affect the nature of the product.

Reasons for the Decision

Main request

- 1. Admittance into the appeal proceedings
 - 1.1 The appellant argued that the claims of the main request corresponded to granted claims and referred to T 123/85 according to which granted claims could be reinstated. Moreover, according to the appellant, the

main request was filed in reply to the preliminary opinion of the Board regarding the non-compliance of the previous requests with Article 84 EPC and Rule 80 EPC. The main request would furthermore not significantly alter the arguments presented and the same prior art documents were to be discussed.

- 1.2 Regarding decision T 123/85, the Board notes that it no longer applies, because the applicable legislation has changed since this decision was issued. Accordingly, reinstatement of granted claims is not an absolute right of the patent proprietor and the admission of the main request is subject to the Rules of Procedure of the Boards of Appeal (RPBA), see the Case Law of the Boards of Appeal, 9th Edition, 2019, V.A.4.12.13, fourth paragraph.
- 1.3 The main request was filed on 8 April 2022 after notification of the summons to oral proceedings. Its admittance into the appeal proceedings is to be decided on the basis of Article 13(2) RPBA 2020 (Article 25(1) RPBA 2020). Pursuant to Article 13(2) RPBA 2020, amendment to the appellant's appeal case at this late stage of the proceedings shall not be admitted unless there are exceptional circumstances which have been justified with cogent reasons by the appellant.
- 1.4 The Board observes that the preliminary opinion on the issues of Article 84 EPC and Rule 80 EPC did not introduce any new argument and was exclusively based on arguments already provided in the reply to the statement setting out the grounds of appeal. The preliminary opinion of the Board does therefore not constitute any exceptional circumstances which would justify the filing of the main request at this stage of

the proceedings. No further reasons for this late filing were provided by the appellant.

Furthermore the category of the independent claim 1 of the main request (product defined by a parameter) was changed compared to the previous requests on file in appeal proceedings (product defined by its process of preparation). Contrary to the opinion of the appellant, this results in a substantial change of the case, even if the prior art documents to be discussed may remain the same.

- 1.5 Accordingly, the main request is not admitted into the appeal proceedings (Article 13 (2) RPBA 2020).

Admittance of auxiliary requests 1 to 6

2. Since auxiliary requests 1-6 must fail due to a lack of clarity (see below 8. to 10.), a reasoning as to their admittance does not need to be provided here.

Admittance of the objection of lack of clarity

3. The appellant requested the objection of lack of clarity in relation to product-by-process claims not to be admitted into the appeal proceedings for the following reasons:
- the arguments of the respondent were late-filed in the opposition proceedings, and
 - these arguments contradicted the submission of the respondent that the definition of the claimed product by way of a parameter (surface coverage) was not appropriate.
4. The Board observes that the objection of lack of clarity of the product-by-process claims was raised in

appeal proceedings at the earliest possible point in time, *i.e.* in the reply to the statement setting out the grounds of appeal (see point 4. as well as points 7.3 and 8.3). This objection had furthermore already been raised in opposition proceedings on 3 May 2019 in reply to the annex to the summons to oral proceedings and subsequent to the filing of auxiliary request 3 by the appellant on 16 October 2018.

5. Accordingly, the lack of clarity objection in relation to product-by-process claims forms part of the appeal proceedings pursuant to Article 12(4) RPBA 2007 (Article 25(2) RPBA 2020).
6. In this context, the Board notes that any potential inconsistency with another objection of the respondent is not a criteria to exclude this submission of the respondent from the proceedings.
7. Finally for the sake of completeness, the Board observes that, as argued by the respondent, this objection concerns directly the amendment made in the present auxiliary requests, and is thus to be taken into account in line with G 3/14. This was not disputed by the appellant.

Auxiliary request 1

8. Clarity
 - 8.1 Claim 1 of auxiliary request 1 defines the claimed product in terms of its process of manufacture. According to established Case Law (see *e.g.* G 2/12, OJ 2016, A28 and G 2/13, OJ 2016, A29; T 956/04; T 768/08; T 150/12), a product may be defined in such terms only if

- (i) the product itself fulfills the requirements of patentability, and
- (ii) it cannot be otherwise satisfactorily defined by reference to its composition, structure or some other testable parameter.

In the present case, the original claims and the description defined the product by means of a parameter, namely the percentage of surface coverage of carrier particles. During oral proceedings the appellant stated, without any supporting evidence, that the sole feature imparted by the process of manufacture to the claimed product was the partial surface coverage of carrier particles. Since this feature can be defined by a parameter, if the process of manufacture indeed only imparts this feature to the product, then the second criterion defined above is not met.

8.2 Furthermore it is also established case law that, in the case of product-by-process claims, the skilled person should be able to determine either from the claim alone or, by construction of the claim in the light of the description, or by construction in the light of the skilled person's common general knowledge, which identifiable and unambiguous technical features are imparted to the product by the process by which it is defined (see T 967/10, T 1988/12, Case Law of the Boards of Appeal, 9th Edition, 2019, II.A.7.1, last paragraph).

In the present case, as brought forward by the respondent, it is unclear which feature of the product the energy consumption of the blender used in the process affects. In this context, the appellant referred to the passage of the original description on page 8 lines 18-22 which states that the defined low

energy consumption reduces the amount of the energy fed into the powder and thus the possibility of de-mixing of the powder. The Board cannot identify from this passage nor the remaining description which exact technical feature would be imparted to the final product thereby. There is in particular no unambiguous link between the low energy consumption and the surface coverage. Hence, it is unclear whether the imparted feature is solely the partial surface coverage, or the partial surface coverage and any further unidentified characteristic.

- 8.3 Finally, the appellant argued that the lack of clarity objection of the respondent contradicted the remaining submissions of the respondent regarding the alleged non-satisfactory definition with the surface coverage parameter in the context of sufficiency of disclosure. According to the appellant, the feature of the product-by-process was introduced to actually improve the clarity of the claims.

This argument is not convincing. The reasons for the formulation in terms of product-by-process are not relevant when assessing the clarity of the resulting claim.

- 8.4 Hence, auxiliary request 1 does not fulfill the requirements of Article 84 EPC.

Auxiliary request 4

9. Clarity

Claim 1 of auxiliary request 4 is identical to claim 1 of auxiliary request 1. Accordingly, auxiliary request

4 does equally not fulfill the requirements of Article 84 EPC.

Auxiliary requests 2, 3, 5 and 6

10. Clarity

10.1 Claims 1 of auxiliary requests 2, 3, 5 and 6 differ from claim 1 of auxiliary request 1 in that a specific surface coverage was additionally defined. The appellant did not provide any specific arguments regarding these auxiliary requests. The Board considers that the maintenance of the process features in said claims implies that these features impart to the product additional technical features. Such features are however in the present case not unambiguously identifiable, for the reasons detailed above under point 8.2.

10.2 As a result, auxiliary requests 2, 3, 5 and 6 do not meet the requirements of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

E. Duval

Decision electronically authenticated