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**Datasheet for the decision
of 18 October 2023**

Case Number: T 1298/21 - 3.3.05

Application Number: 07848134.8

Publication Number: 2081669

IPC: B01J2/22, B07B1/24, B07B7/06,
A61K9/20, A61J3/06, A61J3/10

Language of the proceedings: EN

Title of invention:
PROCESS AND APPARATUS FOR FOR PRODUCING GRANULES

Patent Proprietor:
Atacama Labs Oy

Opponent:
Omya International AG

Headword:
Granules/ATACAMA

Relevant legal provisions:
EPC Art. 54, 56, 83
RPBA 2020 Art. 12(5)

Keyword:

Sufficiency of disclosure - (yes)

Novelty - main request (yes)

Inventive step - main request (yes) - non-obvious alternative

Discretion not to admit submission - submission admitted (no)

Decisions cited:

T 0149/21

Catchword:



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Case Number: T 1298/21 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 18 October 2023

Appellant: Omya International AG
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 June 2021
rejecting the opposition filed against European
patent No. 2081669 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman E. Bendl
Members: T. Burkhardt
P. Guntz

Summary of Facts and Submissions

I. The opponent's (appellant's) appeal is against the opposition division's decision to reject the opposition against European patent No. 2 081 669 B.

II. The following documents were among those discussed at the opposition stage:

D1	WO 99/25343 A1
D2	WO 99/11261 A1
D3	DE 44 19 153 A1
D4	US 6,432,196 B1
D5	US 6,276,534 B1
D10	"Alpine Air Jet Sieve® 200 LS-N", Hosokawa Alpine, 2001, 1-8
D11	A. J. Lynch, Ch. A. Rowland, "The History of Grinding", Society for Mining, Metallurgy, and Exploration, Inc., 2005, 157-64

III. The opposition division held, *inter alia*, that the patent as granted met the requirements of Article 54 EPC over each of D1, D2 and D4. The claimed subject-matter moreover involved an inventive step in view of D2.

IV. With its statement setting out the grounds of appeal, the appellant further submitted:

D12	"Tumbler Screening Machines", Internet Archive Wayback Machine, retrieved on 17 September 2021
D12a	DE 299 01 833 U1

V. During the appeal proceedings, the patent proprietor (respondent) submitted:

D14 Advert "Minox MTS-1200 - Tumbler screener",
A. Foeth B.V.

VI. The independent claims of the main request (patent as granted) read as follows:

"1. A method for producing granules from a powder, characterized in that a low compaction force is applied to the powder to produce a compacted mass comprising a mixture of fine particles and granules and separating fine particles from the granules by entraining the fine particles in a gas stream in which the compacted mass flows, wherein the direction of the flow of the gas stream is substantially contrary to that of the direction of flow of the compacted mass, wherein the fine particles are separated from the granules by means of an apparatus comprising fractionating means wherein the fractionating means comprises a rotating device along the axis of which the compacted mass is moved in said gas stream."

"15. An apparatus for dry granulation, characterized in that the apparatus comprises compacting means capable of producing low compaction force for compacting a powder to produce a compacted mass comprising a mixture of fine particles and granules and fractionating means adapted to separate fine particles from a compacted mass by entraining the fine particles in a gas stream in which the compacted mass flows, wherein the direction of the flow of the gas stream is substantially contrary to that of the direction of flow of the compacted mass and wherein the fractionating

means comprises a rotating device along the axis of which the compacted mass is moved in said gas stream."

Dependent claims 2 to 14 and 16 to 25 relate to embodiments.

VII. The appellant's arguments at the appeal stage relevant to the present decision can be summarised as follows.

The patent as granted did not meet the requirements of Article 83 EPC.

The requirements of Article 54 EPC were not met in view of each of:

- Example 4 of D1, accounting for D12, D12a or D14
- Example 2 of D1, accounting for D3 and D10
- Example 9 in connection with Example 1 of D2
- Example 3 in connection with Example 1 of D4

A combination of Example 1 (and the corresponding results as shown in Example 5) of D2 with each of D4, D5 and D11 rendered obvious the claimed subject-matter.

VIII. The respondent's arguments at the appeal stage relevant to the present decision can be summarised as follows.

The subject-matter of the granted patent was sufficiently disclosed.

None of the above-mentioned examples disclosed all features of the independent claims of the patent as granted.

Example 1 of D2 in combination with any of the above-mentioned documents did not render the subject-matter of these claims obvious.

- IX. The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed (maintenance of the patent as granted). Alternatively, it requested that the patent be maintained as amended on the basis of:

- one of seven auxiliary requests submitted with the reply to the grounds of appeal
- auxiliary request 8 submitted on 9 January 2023

Reasons for the Decision

1. Sufficiency of disclosure

The patent in suit meets the requirements of Article 83 EPC for the reasons set out below.

- 1.1 In the appellant's view, the patent in suit did not meet the requirements of Article 83 EPC. The invention was defined by numerous functional features. There was not enough guidance in the patent in suit to carry out the invention over the entire scope, in particular to decide which operating conditions for the compaction force, the speed of the rotating device and the flow rate of the gas should be chosen. Hence, too much trial and error was necessary.

The examples of the patent in suit only disclosed:

- one type of powder, namely an ingredient with maize starch (see paragraph [0180])
- one compaction means, namely a roller compactor (see paragraph [0177])
- one fractionating means, namely that of Figure 4

Hence, the invention was not sufficiently disclosed as confirmed by T 149/21.

The only compaction apparatus disclosed yielded ribbons and not granules (see paragraph [0177]).

1.2 However, while the precise operating conditions to be applied depend, for example, on the type of powder, the functional language of the claims puts several limitations by clarifying, for example, that:

- the compaction force has to be adapted to produce a compacted mass comprising a mixture of fine particles and granules
- the flow of the gas stream has to be such that fine particles are separated from the granules, which flow in the gas stream, and entrained.

The patent in suit provides generic guidance e.g. for:

- possible minimum and maximum values of the "low compaction force" (see paragraphs [0046] and [0047])
- the possibility to produce the granules by a flake crushing screen from a ribbon formed in a roller compactor (see paragraphs [0040] and [0139])
- the removal of fines entrained by the gas stream from the fractionating means by a rotating device with apertures (see paragraphs [0059] and [0178] or Figure 4)

- a possible device and its rotation speed used to generate the gas flow (see paragraphs [0138] and [0177])

Paragraph [0076] explains that the resulting granule has a compressed core and a porous coating containing small granules and fine particles. According to paragraphs [0075] and [0079], these particles have both good compressibility and good flowability.

The patent hence explains what happens during the compaction and separation method steps and how the gas stream and the granules interact in the device. Under these circumstances, the skilled person is in a position to carry out the invention throughout the entire scope claimed.

Under these circumstances, a single experimental set-up is sufficient, in contrast to in T 149/21, where the claimed method had explicitly to be able to identify and deal with even unscheduled incidents ("unplanmäßige Walzpause aufgrund eines Störfalls") (see Facts and Submissions III and Reasons 3).

By contrast, in the case at hand, the patent discloses one experimental set-up that can be reproduced. This has not been disputed. For the reasons set out above, the description discloses a technical concept fit for generalisation (Case Law of the Boards of Appeal, 10th edn., 2022, II.C.5.4).

The appellant has provided no evidence to demonstrate that it tried to reproduce the invention but failed. There is hence no evidence for serious doubts substantiated by verifiable facts, and the requirements of Article 83 EPC are met.

Main request

2. Novelty

The main request also meets the requirements of Article 54 EPC for the reasons set out below.

2.1 Claim interpretation

According to claim 1, the "compacted mass" comprises a mixture of granules and fine particles (line 13 on page 23 of the patent in suit). Although the amount of fines decreases as the mixture proceeds through the device (due to fine particles being entrained by the gas stream), the mixture still contains granules and fine particles and therefore continues to fall under the term "compacted mass".

Claim 1 makes clear that the compacted mass has to flow in the gas stream (line 14: "in which the compacted mass flows") and that the flow directions of the compacted mass and the gas stream are substantially contrary (line 15).

In addition, the compacted mass is moved along the axis of the "rotating device" (line 18).

2.2 **Example 4 of D1**

2.2.1 In Example 4 of D1 (see page 10, line 27 to page 11, line 2), a "Minox sieve type MTS 1200" is "equipped with an air jet system". The air jet system has a "rotating perforated blade fixed horizontal under the sieve" causing an air flow that is initially upwards.

The air flow blows off fine particles from the coarse particles, and the fine particles are "sucked downwards through the sieve".

Notwithstanding whether **D10** describes the exact device used in D1, the left-hand figure on page 2 of D10 shows that the presence of a kind of hood over the air jet system causes an upward air flow through a first section of the sieve. This air flow is deflected by a cover and then flows downwards (together with entrained fine particles) through a second section of the sieve.

Hence, only the fine particles flow downwards in a direction "substantially contrary" to that of the air flow from below. In line with this, the sentence bridging pages 10 and 11 of D1 indicates that "the fine particles were ... sucked downwards through the sieve".

By contrast, the coarse particles, which are construed as the "compacted mass", cannot move downwards since they are blocked by the sieve.

Hence, Example 4 of D1 fails to disclose in a direct and unambiguous manner that the flows of the compacted mass and the gas stream are substantially contrary to each other.

2.2.2 In the appellant's view, there was a flow of the compacted mass in a direction substantially contrary to that of the upward gas stream due to inevitable, intermittent up- and downward movements of the compacted mass on the sieve caused by the gas flow in Example 4 of D1.

This is not convincing. Example 4 of D1 is silent on any movement of the compacted mass, let alone up- and

downward movements. Even if, *arguendo*, such movements occurred, the skilled person would not equate them to a flow in a direction substantially contrary to that of the upwardly directed gas stream.

- 2.2.3 The appellant also argued that, upon the introduction of the granules into the air sieve device, there were flows in substantially contrary directions in the Minox sieve type MTS 1200 in Example 4 of D1. This device was at least suitable for operation in such a manner. This was supported by **D12**, **D12a** and **D14**, which should be considered in spite of their late filing.

Even the appellant requested that D14 be considered.

While the board exercises, after the in-depth discussion of D12, D12a and D14, its discretion under Articles 12 and 13 RPBA 2020 by admitting these documents, the appellant's arguments on the merits are not convincing.

Firstly, the device of Example 4 of D1 on the one hand and the devices of D12, D12a and D14 on the other hand are not necessarily identical. Hence, any conclusions drawn from D12, D12a or D14 do not necessarily apply to the device of Example 4 of D1. Thus, it has not been disputed, for example, that the device of D14 is not identical to that of Example 4 of D1 since an air jet system is missing from D14. There is also no proof that the device of D12a is exactly that used in Example 4 of D1. Quite to the contrary, while the figure of D12a discloses three superposed sieves (references 28, 30 and 32), Example 4 of D1 only refers to a single sieve (page 10, line 28: "*The sieve applied had ...*"; page 10, line 30: "*... under the sieve*" (emphasis added

by the board)). This proves that there are Minox MTS 1200 devices in different configurations.

Secondly, Example 4 of D1 does not disclose that the air jet system is operated while granules are simultaneously being introduced into the device, e.g. during the continuous operation of the device. Even 3 kg tablets can be produced batch-wise. It is also not directly and unambiguously disclosed that the air jet system of Example 4 of D1 is *suitable* for operation in such a manner, e.g. during the continuous operation of the device. D12 indicates that an "anti-blinding system" is necessary for continuous operation (D12, left-hand column, third paragraph). While it has not been disputed that the air jet system of Example 4 of D1 constitutes an "anti-blinding system", it is not clear that the presence of an anti-blinding system alone is sufficient to render a device suitable for continuous operation and that no further requirements are necessary.

Thirdly, even if it were possible to introduce the compacted mass while the air jet system was working, substantially contrary flows of the compacted mass and the gas stream would still not be directly and unambiguously disclosed. It could well be that the compacted mass enters the device from above through the central opening in the cover while air comes upwards from below the sieve. However, this does not exclude that subsequently on the sieve, i.e. when the compact mass and the gas stream are in contact with each other (as implied by claim 1, line 14), the flows are instead co-current, e.g. towards a lateral outlet.

2.3 **Example 2 of D1**

2.3.1 In Example 2 of D1, an Alpine 200 LS-N air sieve is used. No constructional details of this sieve are disclosed.

In the appellant's view, documents D3 and D10 showed that this device comprised any features not explicitly disclosed in Example 2 of D1.

However, Example 2 of D1 does not anticipate the subject-matter of the independent claims of the patent in suit either.

D3 is a patent document, and there is no indication that the devices of D3 and Example 2 of D1 are identical. For reasons similar to those indicated above for the Minox MTS 1200 device of Example 4, flows of the compacted mass and the gas in substantially contrary directions are also not disclosed in D3.

In fact, the operation of a Minox MTS 1200 air sieve and an Alpine 200 LS-N air sieve is similar. In D3 (see in particular Figures 1 and 2), air is also passed upwards from nozzle 7 through sieve 3 and entrains fine particles (column 1, lines 7 to 23). These fine particles (but not the compacted mass, which is still on the sieve) pass downwards through sieve 3 and are removed via outlet 35. Flows of the compacted mass and the gas in substantially contrary directions on the sieve are not disclosed.

Nor are contrary flows of the compacted mass and the gas stream directly and unambiguously disclosed in **D10**, its admissibility notwithstanding.

For the reasons indicated above for Example 4 of D1, the device of D10 is also not necessarily *suitable* for generating substantially contrary flows of the gas and the compacted mass upon the introduction of the latter (i.e. when the "plexiglas cover" in the figure on the left-hand side of page 2 of D10 is lifted).

Moreover, as shown by the arrows in the figure of D10, the gas and the fine particles flow horizontally over the sieve, while no flow direction is disclosed for the compacted mass.

2.4 **Example 9** in connection with Example 1 of **D2**

In the appellant's view, Example 9 of D2 also anticipated the subject-matter of the independent claims of the patent in suit.

This example relates to the production of tablets containing amoxicillin granules and potassium clavulanate granules.

The amoxicillin granules are produced according to Example 1 of D2, i.e. using a Minox MTS 1200 air sieve. The appellant acknowledged that there was no difference to Example 4 of D1 in this regard. The reasoning of point 2.2 above therefore applies *mutatis mutandis*.

For the production of the potassium clavulanate granules, an air sieve device with a top sieve and a bottom sieve is used in Example 9 of D2 (page 15, lines 5 to 17). However, even if substantially contrary flow directions of the compacted mass and the gas between the top sieve and the bottom sieve were acknowledged, the use of a "rotating device" for the production of

the potassium clavulanate granules is not disclosed. This has not been disputed.

2.5 Example 3 in connection with Example 1 of **D4**

Example 1 of D4 discloses the compaction of granules, and Example 3 their fractionation by a rotating "drum screen" in which "[s]uction is applied at the top".

Further details of the drum screen of Example 3 of D4 on the prevailing flows are not disclosed.

For the same reasons as above for D1 and D2, Example 3 of D4 also fails to disclose at least substantially contrary flow directions of the gas and the compacted mass.

3. Inventive step

For the reasons set out below, the main request also fulfils the requirements of Article 56 EPC.

3.1 The invention relates to a method and apparatus for the production of granules and tablets (paragraph [0001]).

3.2 It has not been contested that **D2** is the closest prior art.

For inventive step, the appellant referred to the embodiment of Example 1 of D2 and the corresponding flowability results disclosed in Example 5.

Since D2 also relates to a method and an apparatus for producing granules (see the examples, for instance), it

is indeed a reasonable starting point for assessing inventive step.

Since a Minox air sieve MTS 1200 is used in Example 1 of D2, the situation is the same as for Example 4 of D1, i.e. there is no direct and unambiguous disclosure of contrary flow directions of the gas stream and the compacted mass in the gas stream, let alone that the compacted mass is moved in the gas stream along the axis of the rotating device (see point 2.2 above).

- 3.3 According to the patent in suit, the problem to be solved is the provision of a method and an apparatus with an improved compromise between flowability and compressibility (see paragraphs [0095] and [0193]).
- 3.4 The main request proposes solving this problem by the method of claim 1 and the apparatus of claim 15, characterised in substantially contrary directions of the flows of the gas stream and the compacted mass in the gas stream, where the compacted mass is moved in the gas stream along the axis of the rotating device.
- 3.5 Whether the effect of an improved compromise between flowability and compressibility is achieved over the entire range claimed (notably without the requirement of a specific gas flow velocity) is moot since, as is explained below, an inventive step is to be acknowledged even if the technical problem to be solved is reformulated as providing an alternative method/apparatus for producing granules from a powder.
- 3.6 In the appellant's view, a combination of Example 1 of D2 with D4, D5 or D11 resulted in the subject-matter of the independent claims.

However, contrary to the requirements of Article 12(3) RPBA 2020, the appellant has failed to substantiate the objection based on the combination with **D4**. Hence, this objection is not admitted (Article 12(5) RPBA 2020).

The skilled person, starting from Example 1 of D2, would not consider **D5**. While Example 1 of D2 aims at producing granules by removing fines from a compacted mass (page 7, lines 20, 22 and 27 to 29), D5 uses "dispersion disk(s) ... to initially break up the feed powder". However, the skilled person starting from Example 1 of D2 and trying to *produce* granules would not consider a process that *breaks up* the compacted mass.

Even if, *arguendo*, the skilled person did consider D5, they would not arrive at the claimed subject-matter since D5 does not disclose the missing feature either. In accordance with Figure 1 (see also column 5, line 21 to column 6, line 54), raw material, such as a compacted mass, is entered via inlet 3 "at an upper portion of the housing" and directed towards a "dispersion disk 8" with "dispersion blades 9" rotating around a *vertical* axis. Air is injected from below through "air inlets 25". As a result of the "centrifugal force", the coarser particles (equated to the compacted mass of claim 1) are *horizontally* "propelled toward the outer circumference of the dispersion disk 8" (column 9, lines 38 to 43). There is thus no direct and unambiguous disclosure of flows of compacted mass and gas in substantially contrary directions, let alone of a movement of "the compacted mass" in the gas stream "along the axis" of a rotating device.

The skilled person, when starting from Example 1 of D2, would not consider the separator of Figure 9.15 of **D11** either, its admissibility notwithstanding. While D2 deals with the production of pharmaceutical granules/tablets (e.g. page 1, lines 9 to 13), D11 deals with "high-tonnage processes" involving the grinding and classification of bulk materials such as cement and coal (page 157, end of the first paragraph of section "AIR CLASSIFIERS"). Moreover, in the processes of D11, "weak compacts are broken" by baffles (paragraph bridging pages 158 and 159). Yet, the skilled person would not consider processes likely to break up the granules they intend to produce.

Hence, the subject-matter of claims 1 and 15 involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Vodz

E. Bendl

Decision electronically authenticated