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Datasheet for the decision of 19 December 2019

Case Number: T 1741/16 - 3.2.02

Application Number: 09786382.3

Publication Number: 2427166

IPC: A61J3/10

Language of the proceedings: EN

Title of invention:
TABLET PRODUCTION MODULE AND METHOD FOR CONTINUOUS PRODUCTION OF TABLETS

Patent Proprietor:
Gea Pharma Systems Limited

Opponents:
Gebrüder Lödige Maschinenbaugesellschaft mbH
Glatt GmbH
L. B. Bohle Maschinen + Verfahren GmbH
Hosokawa Micron B.V.
Fette Compacting GmbH (intervener)
Korsch AG (intervener)

Headword:

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 111(1)
RPBA Art. 13(1), 13(3)

Keyword:
Novelty - main request, auxiliary requests 2 and 9 (no)
Inventive step - auxiliary request 7 (no)
Late-filed auxiliary requests 12 and 13 - admitted (no)
Appeal decision - remittal to the department of first instance (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 1741/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 December 2019

Appellant: (Opponent 1)	Gebrüder Lödige Maschinenbaugesellschaft mbH Elsener Strasse 7-9 D-33102 Paderborn (DE)
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Appellant: (Opponent 4)	Hosokawa Micron B.V. Gildenstraat 26 7005 BL Doetinchem (NL)
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Party as of right: (Opponent 3)	L. B. Bohle Maschinen + Verfahren GmbH Industriestrasse 18 59320 Ennigerloh (DE)
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Intervener: (Opponent 5)	Fette Compacting GmbH Grabauer Straße 24 21493 Schwarzenbek (DE)
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Representative:	Hertin und Partner Rechts- und Patentanwälte PartG mbB Kurfürstendamm 54/55 10707 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 June 2016 rejecting the opposition filed against European patent No. 2427166 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	L. Bühler
Members:	D. Ceccarelli
	M. Stern

Summary of Facts and Submissions

I. Opponents 1, 2 and 4 have appealed against the Opposition Division's decision, posted on 3 June 2016, to reject the oppositions against European patent No. 2 427 166. The patent was opposed on the grounds of insufficient disclosure, added subject-matter, lack of novelty and lack of inventive step.

II. Opponents 5 and 6 intervened in the opposition appeal proceedings following the institution of proceedings on 12 July 2018 regarding the infringement of the patent against them before the regional court (Landgericht) of Düsseldorf (Germany).

III. No objections to the admissibility of the appeals or the interventions have been raised by the respondent/ patent proprietor.

IV. The Board summoned the parties to oral proceedings and provided its preliminary opinion in a communication dated 24 September 2019.

V. Oral proceedings took place on 18 and 19 December 2019.

The appellant/opponent 1 (opponent 1), the appellant/ opponent 2 (opponent 2), the appellant/opponent 4 (opponent 4), the intervener/opponent 5 (opponent 5) and the intervener/opponent 6 (opponent 6) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent/patent proprietor (proprietor) requested that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary requests 2, 7 and 9, filed on 18 November 2019, and 12 and 13

filed during the oral proceedings. Auxiliary requests 1, 3 to 6, 8, 10 and 11, all filed on 18 November 2019, were withdrawn.

VI. The following documents are mentioned in the present decision:

D31: JP-A-2008 183168;
D86: English translation of D31.

VII. **Claim 1 of the patent as granted** reads as follows:

"A module for production of tablets, the module comprising:

at least one inlet for an active pharmaceutical ingredient or API;
at least one inlet for an excipient;
at least one mixing unit;
a tablet press; and
at least one outlet for tablets;
said inlets being in fluid communication with an inlet of the at least one mixing unit, an outlet of the at least one mixing unit is in fluid communication with an inlet of the tablet press, and an outlet of the tablet press is in fluid communication with the outlet for tablets;

characterized in
that the module is contained;
that at least one analytical sensor is provided, said at least one analytical sensor being positioned to analyse the contents or properties upstream of the tablets press, and
that said inlets comprise a releasable inlet conduit (2; 21) for an active pharmaceutical ingredient or API

and a releasable inlet conduit (3; 31; 31a, 31b) for an excipient, and said outlet a releasable outlet port (7; 73)) for tablets, such that the respective inlet conduits and outlet port are generally closed but may be opened to allow application of API and excipients to the module or remove tablets from the module, respectively, the releasable inlet conduits being in fluid communication with the inlet of the mixing unit (4; 41, 42, 43, 44, 45, 46, 47), and the outlet of the tablet press (6) is in fluid communication with the releasable outlet port for tablets."

Claim 1 of auxiliary request 2 reads as claim 1 of the patent as granted except that reference numeral 73 has been changed to 71 and after the word "contained" the following expression has been introduced:

"and has a level of containment below 100 mcg/m^3".

Claim 1 of auxiliary request 7 reads as claim 1 of the patent as granted except that reference numeral 73 has been changed to 71 and the following expression has been introduced at the end of the claim:

"and further comprising a control unit (8), which control unit is capable of receiving data from the at least one analytical sensor (51, 52, 53), and the control unit (8) is adapted to send commands to the inlets for API and excipient(s) and to the mixing unit (4; 41, 42, 43, 44, 45, 46, 47) and to the tablet press (6) and to control the speed of the tablet press".

Claim 1 of auxiliary request 9 reads as follows:

"A method for continuous production of tablets, including the following steps:

providing a contained module comprising at least two inlets, at least one mixing unit, at least one analytical sensor, a tablet press, and at least one outlet for tablets;

feeding an active pharmaceutical ingredient or API to one of said at least two inlets;

feeding an excipient to the other of said at least two inlets;

mixing the material stream comprising the API and the excipient in said at least one mixing unit;

measuring parameters of the contents of the material stream with said at least one analytical sensor upstream of the tablet press;

controlling said two inlets and/or said mixing unit in response to the parameters measured;

continuously supplying the tablet press with the material stream;

controlling the speed of the tablet press in response to the parameters measured upstream of the tablet press, and

discharging tablets at said at least one outlet, wherein said inlets comprise a releasable inlet conduit (2; 21) for an active pharmaceutical ingredient or API and a releasable inlet conduit (3; 31; 31a, 31b) for an excipient, and said outlet a releasable outlet port (7; 71)) for tablets, such that the respective inlet conduits and outlet port are generally closed, but may be opened to allow application of API and excipients to the module or remove tablets from the module, respectively, the releasable inlet conduits being in fluid communication with the inlet of the mixing unit (4; 41, 42, 43, 44, 45, 46, 47), and the outlet of the tablet press (6) is in fluid communication with the releasable outlet port for tablets."

Claim 1 of auxiliary request 12 reads as claim 1 of the

patent as granted except that reference numeral 73 has been changed to 71 and after the word "contained" the following expression has been introduced:

"by designing the individual parts of the process equipment to be contained, all in all making up a module in the sense of containment".

Claim 1 of auxiliary request 13 reads as claim 1 of auxiliary request 7 except that after the word "contained" the following expression has been introduced:

"by designing the individual parts of the process equipment to be contained, all in all making up a module in the sense of containment".

VIII. The arguments of the opponents, where relevant to the present decision, may be summarised as follows:

Patent as granted

The subject-matter of claim 1 of the patent as granted was not novel over D31. In particular, D31 disclosed a module for the production of tablets (paragraph [0001] of D86). The module was contained within the meaning of claim 1 since it was installed in a clean room (paragraph [0009] of D86). Such a form of containment was contemplated by the patent itself (paragraph [0027]). The module comprised an analytical sensor (56, Figure 1, as explained in paragraphs [0035] and [0036] of D86), inlets for active pharmaceutical ingredients and additives (from containers 10a to 10c in Figure 1, as explained in paragraph [0019] of D86) and an outlet for tablets (paragraph [0009] of D86). The fact that material was transported from raw material containers

through the module to the outlet by air transportation pipes (paragraph [0011] of D86) implied that the inlets and the outlet could be opened and closed, being therefore generally closed and releasable within the meaning of claim 1. The claim did not require that the inlets and the outlet form an interface with the exterior of the clean room. The latter was simply the means by which the contained module was obtained.

Auxiliary request 2

The subject-matter of claim 1 of auxiliary request 2 was also not novel over D31, since the clean room in which the module for production of tablets was installed inherently provided a level of containment as defined in the claim.

Auxiliary request 7

The subject-matter of claim 1 of auxiliary request 7 was not inventive over D31. D31 disclosed a control unit (120 in Figure 1, as explained in paragraphs [0025] and [0026] of D86), capable of receiving data from the analytical sensor and adapted to send commands to a mixing unit and a tablet press of the module (paragraph [0037] of D86) and to control the speed of the tablet press (paragraph [0025] of D86). If it was considered that D31 did not directly and unambiguously disclose that the control unit was adapted to send commands to the inlets, this was at least obvious in order to increase the automation of the module of D31.

Auxiliary request 9

The subject-matter of claim 1 of auxiliary request 9 was not novel over D31. D31 disclosed a method for the continuous production of tablets (paragraphs [0025] and [0026] of D86) comprising the steps defined in the claim. In particular, claim 1 did not require a control unit to send commands to the inlets of the module.

Auxiliary requests 12 and 13

Auxiliary requests 12 and 13 had been filed at the latest possible stage of the appeal proceedings for no justifiable reason. The objections leading to the refusal of the higher-ranking requests had been known to the proprietor since at least July 2017. For reasons of fairness and procedural economy, auxiliary requests 12 and 13 should not be admitted into the proceedings.

Remittal of the case

The case should not be remitted to the department of first instance, but a final decision should be taken by the Board.

IX. The arguments of the proprietor, where relevant to the present decision, may be summarised as follows:

Patent as granted

The subject-matter of claim 1 of the patent as granted presented a number of differences over D31. Firstly, the system of D31 was not a contained module within the meaning of the invention, as explained in column 8, lines 34 to 39 of the patent, because it needed to be enclosed in a clean room. It was not the intention of

the proprietor to include such a measure for providing containment in the scope of protection of the claim. Furthermore, Figure 1 of D31 only disclosed one inlet to the system, and no inlets to the clean room. Finally, the inlet for powder and the outlet for tablets disclosed in D31 did not comprise any releasable, generally closed, inlet conduits or outlet port, respectively, as described in paragraph [0022] of the patent.

Auxiliary request 2

The subject-matter of claim 1 of auxiliary request 2 further defined the level of containment of the claimed module, which was not disclosed in D31.

Auxiliary request 7

D31 did not disclose a control unit as defined in claim 1 of auxiliary request 7. More specifically, the control unit disclosed in D31 was not adapted to send commands to the inlets and the outlet, and was not adapted to control the speed of the tablet press. The distinguishing features over D31 addressed the objective technical problem of improving the overall operation of the module, at the same time reducing the risk to personnel by ensuring the containment of the module. Providing these features in the system of D31 would require its complete re-design. Hence, it was not an obvious measure for the skilled person.

Auxiliary request 9

Claim 1 of auxiliary request 9 was directed to a method for the continuous production of tablets, which required a continuous supply of material. The system of

D31 comprised a buffer tank 18 (Figure 1), which implied a series of batch processes. This was different from fully continuous operation, approaching a steady state, which the patent was intended for.

Auxiliary requests 12 and 13

Auxiliary requests 12 and 13 comprised a feature recited in paragraph [0027] of the patent as granted and had been filed in response to the surprising conclusion of the Board that the patent could not be maintained on the basis of higher-ranking requests. The Opposition Division in the impugned decision had reached a different conclusion. The preliminary opinion of the Board, in the communication accompanying the summons to oral proceedings (point 4.2), also stated that D31 did not appear to deprive the subject-matter of claim 1 of the patent as granted of novelty. In this respect it was not significant when and whether the opponents had raised the objections that lead to the refusal of the higher-ranking requests. For these reasons auxiliary requests 12 and 13 should be admitted into the proceedings.

Remittal of the case

The case should be remitted to the Opposition Division for further prosecution, since none of the auxiliary requests were dealt with at first instance.

Reasons for the Decision

1. The appeals and the interventions are admissible.

2. The invention

The invention relates to a module for the production of tablets and a method for the continuous production of tablets.

The module comprises an inlet for an active pharmaceutical ingredient (API), an inlet for an excipient, a mixing unit, an analytical sensor, a tablet press and an outlet for tablets. In the patent as granted the module is claimed to be "contained", the inlets comprise releasable inlet conduits and the outlet comprises a releasable outlet port such that the inlets and the outlet are generally closed but may be opened to allow application of the API and excipients or remove tablets. According to the description, column 9, lines 18 to 22 of the patent in suit, the term "contained" means "dust-tight" according to "the SMEPAC test".

The claimed module and method should improve the efficiency of the production of tablets and provide processes that are environmentally safer and pose a reduced risk to an operator of the process (column 1, lines 52 to 55 of the patent).

3. Patent as granted

D31 relates to a tablet manufacturing system. As explained in particular in paragraphs [0009] and [0019] of D86, the system is for installation in a clean room and comprises a mixing unit (granulator 12 in Figure 1), a tablet press (tableting equipment 22 in Figure 1), inlets for powder raw material (from containers 10a to 10c in Figure 1) and an outlet for tablets.
The inlets are in fluid communication with an inlet of

the mixing unit, an outlet of the mixing unit is in fluid communication with an inlet of the tablet press, and an outlet of the tablet press is in fluid communication with the outlet for tablets (Figure 1 and last sentence of paragraph [0019] of D86).
The system further comprises an analytical sensor positioned to analyse the properties upstream of the tablet press (56, Figure 1, as explained in paragraph [0034] of D86).

Contrary to the view of the proprietor, the system of D31 is considered to be a contained module within the meaning of claim 1.

As pointed out by the opponents, the patent in suit, in paragraph [0027], provides a broad definition of a "contained module":

"the module may be contained by being in a confined space, but the concept of 'containment' includes designing the individual parts of the process equipment to be 'contained', all in all making up a 'module' in the sense of containment".

The installation of the system of D31 in a clean room meets such a definition, as the clean room provides a confined space from which dust is prevented from reaching adjacent working areas.

It follows that, as the opponents argued, the clean room itself is the means which render the system of D31 a contained module within the meaning of claim 1 of the patent as granted. Any speculation on what the proprietor's intention could have been is of little relevance in view of the explicit teaching of the patent as indicated above.

The provision of a plurality of raw material containers in D31 (Figure 1 and paragraph [0019]) implies at least one inlet for an active pharmaceutical ingredient and one inlet for an excipient, since these are the typical constituent ingredients of tablets. The fact that the inlets are not inlets to the clean room, as the proprietor argued, is of no relevance, since the claim merely requires inlets of the contained module. As explained above, the clean room is merely the means which render the system of D31 a contained module within the meaning of claim 1 of the patent as granted.

Finally, as the opponents pointed out, D31 discloses that the flow of material from the raw material containers to the outlet of the tablet press is provided by transportation pipes (paragraph [0011] of D86). Such a transportation system is based on the creation of pressure gradients along the transportation line, which necessitate the possibility of opening and keeping closed the inlets and the outlet of the system. This implies releasable, generally closed inlet conduits and a releasable, generally closed outlet port within the meaning of claim 1.

If follows that D31 discloses all of the features of claim 1.

As a consequence, the patent cannot be maintained as granted for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1.

4. Auxiliary request 2

Compared with claim 1 of the patent as granted, claim 1 of auxiliary request 2 additionally requires the

contained module to have a level of containment below 100 mcg/m^3. However, a clean room as taught in D31 provides a complete physical separation between the module and adjacent working areas which is a barrier to dust reaching virtually any containment level, and consequently a level as claimed. Hence, the subject-matter of claim 1 of auxiliary request 2 is also anticipated by D31.

It follows that the patent cannot be maintained on the basis of auxiliary request 2 for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1.

5. Auxiliary request 7

Compared with claim 1 of the patent as granted, claim 1 of auxiliary request 7 additionally defines a control unit.

As the opponents submitted, D31 discloses a control unit (120 in Figure 1, as explained in paragraphs [0025] and [0026] of D86), capable of receiving data from the analytical sensor and adapted to send commands to a mixing unit and a tablet press of the module (paragraph [0037] of D86), as it can stop operations.

Contrary to the proprietor's view, the control unit of D31 is also adapted to control the speed of the tablet press. Paragraph [0025] of D86 discloses that the control unit can "change an apparatus operating speed" and that complete continuous operation of the tablet manufacturing system is desirable. Under continuous operation, changing one operating speed inherently requires, at least after some time due to the presence of a buffer tank in the line, the change of the speed

of the tablet press.

D31 does not directly and unambiguously disclose that the control unit is adapted to send commands to the inlets and the outlet of the tablet manufacturing system. It cannot be excluded that the opening and closing of the inlets and the outlet could be performed independently of the control unit, for example using a different control system solely responsible for the transportation of material along the manufacturing line.

The Board agrees with the opponents that this distinguishing feature addresses the objective technical problem of increasing the automation of the system of D31, since it provides the technical effect of having a single controller for managing the whole system.

The problem formulated by the proprietor cannot be accepted, as sending commands to the inlets and the outlet as such has nothing to do with the level of containment of the system.

In the Board's view, using control unit 120 for controlling all the elements of the tablet manufacturing system of D31 is obvious in the light of the objective technical problem, as that control unit is already present and controls several other elements of the system. Specifically, the fact that the control unit is already present in the system excludes the necessity of a major re-design.

It follows that the subject-matter of claim 1 of auxiliary request 7 is not inventive over D31 alone.

As a consequence, the patent cannot be maintained on the basis of auxiliary request 7 for lack of inventive step (Article 56 EPC) of the subject-matter of claim 1.

6. Auxiliary request 9

Claim 1 of auxiliary request 9 is directed to a method for the production of tablets.

As explained above, the system of D31 comprises all the structural elements recited in the claim. It is common ground that the normal mode of operation of that system anticipates most of the claimed features too. In particular, there is no requirement in claim 1 that the inlets and the outlet be controlled by a control unit.

The only dispute is whether the method of operation of the system of D31 is for the continuous production of tablets. The proprietor argued that this was not the case, due to the presence of a buffer tank (18, Figure 1) in the system of D31 which implied that batches of tablets were produced, in contrast to fully continuous operation according to the invention.

The Board notes that there is no requirement for "fully continuous operation" in the claim, whatever this expression may mean. Moreover, the presence of a buffer tank in D31 does not exclude continuous production, but is rather for ensuring such a production. In paragraph [0020] of D86 it is explained that the granulator of D31 may adopt a batch method. Paragraph [0024] of D86 reads:

"...Since the discharge amount from the granulating apparatus (12) is fluctuated due to the batch method, the buffer tank absorbs the fluctuations so that the

next process can be operated continuously..."

Paragraph [0025] goes on to explain that "*basically complete continuous operation [...] is desirable for the system to improve the operating rate*".

This leads the Board to the conclusion that the system of D31 is for the continuous production of tablets within the meaning of claim 1 of auxiliary request 9.

As a consequence, the patent cannot be maintained on the basis of auxiliary request 9 for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1.

7. Auxiliary requests 12 and 13

Auxiliary requests 12 and 13 constitute amendments to the proprietor's case, made during the oral proceedings. Under Article 13(1) RPBA their admission into the appeal proceedings is at the Board's discretion, which is to be exercised in view of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Under Article 13(3) RPBA they should not be admitted if they raise issues which the Board or the other parties cannot reasonably be expected to address without an adjournment of the oral proceedings.

The Board notes that the proprietor filed auxiliary requests 12 and 13 at the last possible moment, on the second day of the oral proceedings, after the Board had reached its conclusions on the patent as granted and auxiliary requests 2 and 7. Moreover, claim 1 of each of auxiliary requests 12 and 13 does not even derive

from a combination of granted claims, but comprises a feature extracted from the description. This increases the difficulty for the parties of dealing with the subject-matter of these requests.

The proprietor's argument that the late filing of the requests was in response to the surprising conclusion of the Board that the patent could not be maintained on the basis of higher-ranking requests is not convincing.

First of all, the objection of lack of novelty based on D31 was first raised by the opponents as early as July 2017.

Moreover, in the communication accompanying the summons to oral proceedings (point 4.1, last paragraph) it was made clear that the preliminary view expressed in point 4.2 depended on whether a "contained module" according to claim 1 of the patent as granted had to satisfy some limitations set out in the description:

"only if it is concluded that a contained module within the meaning of the claims must satisfy the definition and the limitations set out in the description, would the following observations apply".

In view of this paragraph it cannot be considered surprising that the Board concluded otherwise.

For these reasons the Board, exercising its discretion under Article 13(1) and (3) RPBA, decides not to admit auxiliary requests 12 and 13 into the appeal proceedings.

8. Remittal of the case

Under Article 111(1) EPC, following the examination of the allowability of the appeal, the Board retains its discretion to exercise any power within the competence of the department responsible for the decision appealed or remit the case to that department for further prosecution.

The Board notes that the Opposition Division dealt with the objection of lack of novelty in view of D31, and concluded that novelty was given. The Opposition Division went on to examine all the grounds for opposition invoked by the opponents and rejected the oppositions. Clearly, there was no need for the Opposition Division to examine the auxiliary requests filed by the proprietor.

The fact that the Board reached a different conclusion on the objections based on D31 does not imply, in view of Article 111(1) EPC, that the proprietor be given a second chance, with auxiliary requests to be considered at first instance. In fact, Article 111(1) EPC does not provide an absolute right for a party to be given two degrees of jurisdiction.

With due consideration also of the fact that proceedings for infringement of the patent are running in Germany the Board, in the exercise of its discretion under Article 111(1) EPC, decides not to remit the case but to reach a final decision.

9. Since there is no valid request on file which fulfils all the requirements of the EPC, the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe L. Bühler

Decision electronically authenticated