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**Datasheet for the decision  
of 21 June 2023**

**Case Number:** T 0897/19 - 3.2.01

**Application Number:** 10782770.1

**Publication Number:** 2504797

**IPC:** G06M1/24, G06M1/16, A61M5/00

**Language of the proceedings:** EN

**Title of invention:**  
DOSE COUNTER

**Patent Proprietor:**  
Kindeva Drug Delivery L.P.

**Opponent:**  
BOEHRINGER INGELHEIM INTERNATIONAL GMBH /  
BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(b)  
RPBA Art. 12(4)  
RPBA 2020 Art. 25(2)

**Keyword:**

Grounds for opposition - insufficiency of disclosure (no)  
facts not admitted by the opposition division - admitted (no)  
Late-filed facts - admitted (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

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**Case Number: T 0897/19 - 3.2.01**

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 21 June 2023**

**Appellants:** BOEHRINGER INGELHEIM INTERNATIONAL GMBH /  
(Opponents) BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG  
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**Respondent:** Kindeva Drug Delivery L.P.  
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**Representative:** Mathys & Squire  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
25 January 2019 concerning maintenance of the  
European Patent No. 2504797 in amended form.**

**Composition of the Board:**

**Chairman** V. Vinci  
**Members:** S. Mangin  
S. Fernández de Córdoba

## **Summary of Facts and Submissions**

- I. The appeal was filed by the appellants (opponents) against the interlocutory decision of the Opposition Division finding that, on the basis of the main request, the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. The Opposition Division maintained the patent on the basis of the main request. The Opposition Division held that:
- (1) the patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art,
  - (2) the late filed objections of lack of novelty of claim 1 in view of D2 (GB 2372541 A), D7 (WO 03/107269 A1), D8 (WO 2010/023233 A1) and D9 (WO 2007/124406 A2) were not to be admitted in the proceedings pursuant to Rule 116(1) EPC.
- III. Oral proceedings were held before the Board on 21 June 2023 per videoconference.
- IV. The appellants (opponents) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or in the alternative that the patent be maintained on the basis of one of the first to sixth auxiliary requests submitted with the reply to the statement of grounds of appeal (the fifth and sixth auxiliary requests correspond to the first and second auxiliary requests submitted in opposition proceedings)

or of the seventh to eleventh auxiliary requests submitted with the letter dated 17 April 2023.

V. Claim 1 of the main request (with the feature numbering used by the proprietor on page 8 of the reply to the statement of grounds of appeal) reads as follows:

**M1** A dose counter (200) for use with an inhaler (5), the inhaler comprising a container for medicament, the inhaler being equipped with a reciprocal actuation means to dispense a dose of medicament therefrom, the dose counter comprising:

**M2** a counter member (240) constructed and arranged to undergo a predetermined counting motion each time the dose is dispensed,

**M3** the counting motion comprising at least a first vertical or essentially vertical movement;

**M4** a count-indicating member (250) constructed and arranged to undergo a predetermined counting motion each time a dose is dispensed,

**M5** the count-indicating member comprising a first region for interaction with the counter member;

**M6** wherein the counter member comprising a first region for interaction with the count-indicating member

**M7** said first region of the counter member comprising at least one surface that is engaged with the at least one surface of said first region of the count-indicating member;

**M8** and wherein said first region of the counter member and said first region of the count-indicating member are configured and arranged, such that said count indicating member completes its count indicating motion in coordination with the counting motion of said counter member and characterized in that

**M9** during and induced by said first movement of the counter member the count indicating member undergoes a rotational or essentially rotational movement and **M10** wherein the dose counter further comprises an indexing member (230) constructed and arranged to undergo reciprocal movement coordinated with the reciprocal movement between the actuation means and the container and to induce at least said first vertical or essentially vertical movement of the counter member.

VI. Further documents are referred to in the present decision:

D1: WO2007/124406

D3: US6752153 B1

D4: WO2005/060535 A2

D9: US5482030

D11: US5564414

D13: WO2005/060917 A1

D14: WO2005/113044 A1

D15: WO2004/056416 A1

### **Reasons for the Decision**

1. Main request - Sufficiency of disclosure (Article 100(b) EPC)

With regard to sufficiency of disclosure of the invention, in the oral proceedings the parties referred to their written statements. The Board has thus no reason to deviate from its preliminary opinion expressed in their communication pursuant Article 15(1) RPBA, which is reproduced below:

The Opposition Division held that the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person. The Board

does not see any reason why it should deviate from the opinion of the Opposition Division.

The appellants (opponents) maintained their objection of insufficiency of disclosure and referred generally to the submissions made during the opposition proceedings.

It is established case law that the mere reference to the earlier submissions including the arguments put forward at the oral proceedings before the Opposition Division without actually dealing or entering into a discussion of the reasons given in the decision under appeal by the Opposition Division for arriving at its decision is not enough to substantiate a ground of appeal (see Case Law of the Boards of Appeal 10th edition V.A.2.6.5 "References to earlier submissions").

2. Main request - Admissibility of the objections of lack of novelty in view of D2, D7, D8 and D12 - Article 12(4) RPBA 2007 (Article 25(2) RPBA 2020)

The lack of novelty objections against the subject-matter of claim 1 in view of D2, D7, D8 and D12, which were not admitted in the opposition procedure are not admitted in the appeal proceedings.

- 2.1 The appellants (opponents) argued that the patent was opposed in its entirety on the ground that the subject-matter of the European patent was not patentable under Articles 52 to 57 EPC and that documents D1-D16 were filed with the notice of opposition. Thus lack of novelty and inventive step was formally raised against the subject-matter of claim 1 of the main request, which is a combination of granted claim 1 and 4, at the outset of the opposition procedure. During oral

proceedings in opposition the appellants (opponents) only presented new arguments, which could not be disregarded under Article 114(2) EPC as it only concerned facts and evidence.

Consequently, the novelty objections in view of D2, D7, D8 and D12 should have been considered in full, independently of the question of whether the underlying documents were prima facie relevant, since they were based on facts and evidence submitted with the notice of opposition.

2.1.1 Furthermore the appellants (opponents) argued that according to Article 114(1) EPC, the Opposition Division should have examined of its own motion whether the subject-matter of claim 1 of the main request was anticipated by the state of the art mentioned in the notice of opposition even if in the notice of opposition the lack of novelty of granted claim 4 was not substantiated.

2.1.2 Finally, the appellants (opponents) claimed that the Opposition Division incorrectly applied the criterion of the prima facie relevance. It did not assess thoroughly the documents and wrongly came to the conclusion that documents D2, D7, D8 and D12 were not prima facie relevant for the novelty of the subject-matter of claim 1.

According to the appellants (opponents) feature M3 "*the counting motion comprising at least a first vertical or essentially vertical movement*" should be interpreted as follows:

- The term "first" was to be associated only with the alternative vertical movement and not to the alternative essentially vertical movement.

- The term "first" did not imply a chronological order. The initial movement of the counting movement could be any type of movement.
- The use of the term "comprising" in feature M3 did not exclude other movement which could take place during the first movement. For example, a rotation movement could take place at the same time as the vertical movement of the counting motion resulting in a spiral movement. This interpretation was in line with dependent claim 2 defining that *"the predetermined counting motion of the counter member includes, independently or simultaneously vertical and rotational movements (...)"*.

Following this interpretation the appellants (opponents) reviewed in substance the prima facie relevance of documents D2, D7, D8 and D12 against the novelty of the subject-matter of claim 1 and came to the conclusion that D2, D7, D8 and D12 were novelty destroying for the subject-matter of claim 1.

2.2 The Board does not agree with the arguments put forward by the appellants (opponents).

2.2.1 While in the notice of opposition the lack of novelty and inventive step of granted claim 4 was formally raised, it was not substantiated. The notice of opposition did not comprise any specific lack of novelty and inventive step objections for granted claim 4. In particular no specific document was indicated for the lack of novelty and inventive step of granted claim 4.

With their reply to the notice of opposition, dated 18 December 2017, the respondent (patent proprietor)

filed the main request, where claim 1 was a combination of granted claims 1 and 4.

The Opposition Division noted in their preliminary opinion, that the appellants (opponents) did not file any novelty and inventive step objections against granted claim 4 in their notice of opposition, such that claim 1 of the main request filed by the respondent (patent proprietor) with the reply to the notice of opposition did not have any objections under Articles 54 and 56 EPC.

In their letter of 25 September 2018, the appellants (opponents) argued that according to feature M3 the counting movement of the counter element comprised a first vertical movement or an (not necessarily first) essentially vertical movement. In the characterising part of claim 1 of the main request, only the variant defined by the first movement was taken up in feature M9, i.e. the alternative "essentially vertical movement" was not further restricted by M9. Therefore, claim 1 was still not novel in view of D2, D8, D9, D11 and D13 and did not involve an inventive step.

2.2.2 The appellants (opponents) only raised novelty and inventive step objections in opposition proceedings against claim 1 of the main request, considering that the added feature in claim 1 (granted claim 4) was not limiting the alternative of the counting motion comprising an essentially vertical movement. If the added feature (granted claim 4) limited the claim, there were no objections. The appellants (opponents) actually acknowledged that the added features of claim 4 were new features in their letter of 25 September 2018 at the beginning of the first full paragraph on page 2 (*"Es wird nicht bestritten, dass*

*der vormalige Unteranspruch 4 an sich neue Merkmale enthält").*

The objections of lack of novelty against claim 1 of the main request, where feature M3 was considered to limit the claim, were only substantiated during the oral proceedings in opposition on 3 December 2018. These new objections, which constituted new facts, were thus filed late and the Opposition Division rightly applied their discretion not to admit these objections using the prima facie relevance criteria.

2.2.3 The Board notes that these new specific novelty objections cannot be considered as mere new arguments but rather amount to new facts. In the notice of opposition nothing more than the grounds (Article 100(a), novelty and inventive step) and the evidence (documents D2, D7, D8 and D12) were mentioned against granted claim 4. The specific novelty objections against claim 1 of the main request based on the pieces of evidence provided in the notice of opposition amount to alleged facts that were only submitted during the oral proceedings in opposition.

2.2.4 Furthermore an investigative approach from the Opposition Division under Article 114(1) EPC is limited in view of the character of the post-grant opposition proceedings under the EPC, which is a contentious proceedings between parties representing opposite interests, who should be given equally fair treatment. It is the responsibility of the opponents themselves to present to the Opposition Division the facts, evidence and arguments in support of the grounds on which the opposition is based.

2.2.5 Late-filed facts should only be exceptionally admitted into the proceedings by the Opposition Division if, *prima facie*, there are clear reasons to suspect that such late-filed material would prejudice the maintenance of the patent in suit. The Opposition Division, in the decision under appeal, explained why documents D2, D7, D8 and D12 were not *prima facie* novelty destroying for the subject-matter of claim 1 (points 40-56 of the appealed decision).

It is established case law that the discretionary power conferred by Article 114(2) EPC and Rule 116(2) EPC necessarily implies that the EPO department of first instance must have a certain degree of freedom in exercising its power. A Board of appeal should only overrule the way in which a department of first instance has exercised its discretion when deciding on a particular case if it concludes that it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way, and has thus exceeded the proper limits of its discretion. It is not the function of a Board to review all the facts and circumstances of the case as if it were in the place of the department of first instance in order to decide whether or not it would have exercised such discretion in the same way (Case Law of the Boards of appeal 10th edition, IV-C-4.5.2 "Review of the discretionary decisions by the boards").

2.2.6 The Opposition Division assessed feature M3 reading "the counting motion comprising at least a first vertical or essentially vertical movement" to be interpreted as the counting motion undergoing a first (in the chronological sense) movement which is either vertical or essentially vertical. It was incorrect to

consider that the term "first" only applied to the vertical movement and not to the essentially vertical movement. The appellants considered the term "movement" to apply to both the alternative "vertical" and the alternative "essentially vertical". Applying a different approach for the term "first" was not consistent.

Furthermore, the term "first" was to be understood as the earliest in a chronological order. i.e. the initial movement, otherwise, the term "first" would be meaningless, i.e. providing no limitation.

Finally, it was incorrect to consider that another movement could be superposed on the first movement such as a rotation which would result in a spiral movement. Indeed the definition of a vertical or essentially vertical movement would be void of any sense if any other movement could be superposed as the resulting movement could result in any type of movement including an essentially horizontal movement.

To sum up, the skilled person, with a mind willing to understand, would interpret feature M3 as meaning that the counter member initially undergoes a pure vertical or essentially vertical movement.

2.2.7 With the above interpretation of claim 1, the Opposition Division applied in a reasonable way their discretionary power not to admit late filed facts under Article 114(2) and Rule 116(1) EPC. They thoroughly assessed the prima facie novelty objections against the subject-matter of claim 1 in view of D2, D7, D8 and D12 as can be seen in the appealed decision. Contrary to the allegation of the appellants (opponents), a review of the appealed decision, shows that a thorough assessment of the prima facie relevance of documents D2, D7, D8 and D12 was made. Reference is made to points 40 to 56 of the appealed decision.

For the same reasons, the appellants' request that the Board exercises their own discretion to admit the objections of lack of novelty based on documents D2, D7, D8 and D12 in the appeal procedure is to be rejected. Further, the Board can neither identify, nor it has been put forward by the appellants, any circumstance of the appeal case which could justify their admittance at the appeal stage.

3. Admissibility of the objections of lack of novelty in view of D1, D3, D4, D9, D11, D13, D14, D15.

The Board holds inadmissible the objections of lack of novelty of claim 1 in view of D1, D3, D4, D9, D11, D13, D14, D15 raised for the first time with the statement of grounds of appeal.

- 3.1 The appellants (opponents) considered that the objections of lack of novelty against documents D1, D3, D4, D9, D11, D13, D14, D15 raised with the statement of grounds of appeal were neither facts nor evidence, but arguments. D1, D3, D4, D9, D11, D13, D14, D15 were submitted with the notice of opposition, opposing the patent in its entirety on the ground of lack of novelty and inventive step. There was thus no reason not to admit these novelty objections against claim 1 of the main request.

Furthermore, the appellants (opponents) explained that they only realised the relevance of these documents regarding the novelty of granted claim 4 and claim 1 of the main request, after the opposition proceedings. Therefore, they could not have substantiated the novelty objections earlier.

Finally the appellants (opponents) detailed why documents D1, D3, D4, D9, D11, D13, D14, D15 were novelty destroying against claim 1 of the main request, thus prima facie relevant against the novelty of the subject-matter of claim 1 of the main request, and were thus to be admitted in the appeal proceedings.

3.2 The Board does not follow the arguments of the appellants (opponents).

The lack of novelty objections raised for the first time with the statement of grounds of appeal against the subject-matter of claim 1 cannot be considered as new arguments, but instead relate to new facts (similarly to the lack of novelty objections not admitted by the Opposition Division). No novelty objections were substantiated in opposition proceedings based on documents D1, D3, D4, D9, D11, D13, D14, D15 against claim 1 of the main request.

According to Article 25(2) RPBA 2020, Article 12(4) RPBA 2007 is applicable in the present case. According to Article 12(4) RPBA 2007, the Board has the power to hold inadmissible facts that could have been presented in the first instance proceedings.

In inter-parte proceedings, the parties have the duty to submit all relevant facts, evidence, arguments and requests as early and completely as possible, especially when such facts and evidence were known to the parties.

In the present case, the novelty objections raised with the statement of grounds of appeal were based on documents known to the appellants (opponents) at the filing of the notice of opposition. The novelty objection against granted claim 4 could thus have been

raised with the notice of opposition or at the latest after the main request was filed, during the opposition proceedings. The appellants (opponents) argued that the relevance of documents D1, D3, D4, D9, D11, D13, D14, D15 against the novelty of claim 1 only appeared after the opposition proceedings. However, the appellants' (opponents') lack of rigor cannot be to the detriment of the respondent (proprietor) having to face new objections up until the appeal proceedings, where the appeal proceedings is actually mainly a judicial review of the decision of the Opposition Division.

4. Admissibility of the objections of lack of inventive step starting from D7 in combination with common general knowledge and starting from D2, D8, D12, D1, D3, D4, D9, D11, D13, D14 and/or D15.

Pursuant to Article 12(4) RPBA 2007, the Board does not admit the various objections of lack of inventive step submitted with the statement of grounds of appeal.

- 4.1 The appellants (opponents) objected that the Opposition Division only examined the subject-matter of the main request with regard to novelty and not with regard to inventive step (see page 5, last paragraph of section I of the statement of the grounds of appeal). In their view it was already requested in the notice of opposition to revoke the patent in its entirety, i.e. also in the scope of the granted claim 4, whereby the fact that the requirements relating to Article 56 EPC (inventive step) were not met was also explicitly mentioned as a reason for opposition.

The appellants (opponents) further raised inventive step objections with the statement of grounds of appeal, starting from D7 in combination with common

general knowledge and starting from all of the other documents presented against the novelty of claim 1 in a very general manner.

4.2 The Board does not agree.

There were no specific lack of inventive step objections regarding granted claim 4 in the notice of opposition. With letter of 25 September 2018, the appellants (opponents) did not either formulate any specific inventive step objection, but argued that the wording of claim 1 according to the main request via alternative M3.2 did not further limit the claim such that the subject-matter of claim 1 was still not new and inventive in the light of documents D2, D8, D9, D11 and D13.

The Opposition Division did not agree with the interpretation of the appellants (opponents) of feature M3 as can be seen in paragraph 49 on page 7 of the appealed decision. Furthermore the appellants (opponents) did not provide any specific inventive step objections during oral proceedings in opposition, nor did they argue that a document was prima facie relevant for inventive step as can be seen from the minutes (see in particular point 12 of the minutes of the opposition oral proceedings ).

Under these circumstances, there was no reason for the opposition division to examine further the subject-matter of claim 1 with regard to inventive step.

For the same reasons as for the novelty objections raised for the first time with the statement of grounds of appeal, the inventive step objections should have been raised in opposition proceedings especially as they were based on documents submitted at the outset of the opposition proceedings, with the notice of opposition. Nothing prevented the appellants

(opponents) from raising inventive step objections against the subject-matter of the main request submitted by the proprietor with their reply to the notice of opposition of 18 December 2017. The appellants (opponents) did not provide any reasons for raising the inventive step objections against the subject-matter of claim 1 of the main request only at the appeal stage. Under these circumstances, there is no reason for the Board to admit the inventive step objections submitted by the appellants with their statement of grounds of appeal.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



A. Vottner

V. Vinci

Decision electronically authenticated