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**Datasheet for the decision
of 15 January 2015**

Case Number: T 1283/11 - 3.2.02

Application Number: 04721094.3

Publication Number: 1603615

IPC: A61M15/00

Language of the proceedings: EN

Title of invention:

IMPROVED DRY POWDER INHALER SYSTEM

Patent Proprietor:

Galephar M/F

Opponent:

(withdrawn)

Headword:

Relevant legal provisions:

EPC Art. 99(1), 100(b), 111(1), 114(1)

Keyword:

Grounds for opposition -
fresh ground for opposition introduced by the opposition
division
Grounds for opposition - insufficiency of disclosure (no)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:

G 0010/91

Catchword:



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Chambres de recours**

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Case Number: T 1283/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 January 2015

Appellant: Galephar M/F
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 20 April 2011
revoking European patent No. 1603615 pursuant to
Article 101(3) (b) EPC.

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

- I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 20 April 2011, to revoke European patent No. 1 603 615.
- II. In its decision, taken during oral proceedings on 6 April 2011, the Opposition Division held that the invention as claimed in claim 1 of the patent as granted was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It followed that the ground for opposition according to Article 100(b) EPC prejudiced the maintenance of the patent as granted.
- III. The patent proprietor had been made aware of the objection based on the ground for opposition according to Article 100(b) EPC three weeks before the oral proceedings and replied to it in writing in advance of the oral proceedings by letter dated 28 March 2011.
- IV. The notice of appeal was received on 10 June 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 26 August 2011.
- V. The opponent withdrew the opposition by letter dated 30 July 2014.
- VI. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted. A former request for reimbursement of the appeal fee was withdrawn by letter dated 29 October 2014.
- VII. Claim 1 of the patent as granted reads as follows:

"A dry powder inhalation system comprising:

(A) at least one micronized active ingredient, optionally in association with excipients, contained in a container, advantageously capsule, said container having an outer surface extending between two end portions intended to be pierced or perforated, and

(B) an dry powder inhaler device comprising a mouthpiece (4), a chamber (B) in which the container is inserted, a perforating system with piercing systems able to pierce or perforate said container at said two end portions, and a return mechanism (6) so as to remove the piercing systems outside of the pierced container, whereby the chamber has a form and a volume greater than the container so as to enable, after removal of the piercing systems outside the container, a rotation of the container during the inhalation,

characterized in that the container is an hydroxypropylmethylcellulose container, and in that the perforating system comprises at least two advantageously substantially identical piercing systems, said piercing systems having an equivalent diameter of not less than 0.8 millimeter (mm), preferably not less than 1 mm, whereby the piercing systems are adapted so that the equivalent diameter of the hole or holes pierced by each piercing system after removal of the piercing system from the hole or holes is from 10 to 31 %, and preferably from 15 % to 26 % of the equivalent diameter of the cross section of the portion of the outer surface of the container to be pierced located between the two pierced end portions, said cross section being located in a plane perpendicular to an axis extending between the end

portions, advantageously a symmetrical axis extending between the end portions." (apparent errors as on file)

VIII. As far as relevant for the present decision, the appellant's arguments may be summarised as follows:

The Opposition Division should not have admitted the ground for opposition according to Article 100(b) EPC, as it had been raised at a very late stage, i.e. "nearly 2 years after the expiry of the time limit laid down in Art. 99(1)". The appellant had been left with only 3 weeks to prepare arguments and evidence to bring forward during the oral proceedings before the Opposition Division. Such a short time was not enough. Had the appellant had more time, he would have proved that the fresh ground was not relevant and, hence, not to be admitted based on decisions G 7/95 and G 9/91. Moreover, the burden of proof of the prima-facie relevance of the fresh ground for opposition, which was a pre-requisite for its admission into the proceedings, was on the opponent, who had not discharged it.

The invention as claimed in claim 1 of the patent as granted was sufficiently disclosed in the patent specification. In particular, the equivalent diameter of the holes pierced by the piercing systems, which was the only term objected to in the impugned decision, caused no problem to the man skilled in the art. The definition of the equivalent diameter of piercing pins was clearly given in the patent, on page 4, lines 17 to 20. To obtain that equivalent diameter knowledge of the area and the perimeter of the pins was required. The given definition equally applied to the equivalent diameter of the holes. Even though the surface in which the holes were pierced was not planar, paragraph [0026] explained that what was important was the "open

passage" of the holes, expressed in mm^2 . It followed that there was no reason to consider that the perimeter of the holes had to be measured in three dimensions. Rather, as indicated in paragraph [0045], the open section of the hole perpendicular to the axis of travel of the piercing pins, extending in two dimensions, was to be measured. The term "equivalent diameter of the holes" did not refer to a newly formulated parameter in the patent but rather to a known parameter also called "hydraulic diameter" or "equivalent hydraulic diameter", these terms being frequently used interchangeably in the art. There were several methods within the skilled person's common knowledge for calculating the open section of the hole as mentioned above. For example, a projection to obtain a 2D image could be made and then the obtained image could be converted into an equivalent circle, or the area of the projection could be obtained by weighing a copy of the image cut from paper of a known surface density. Neither the area nor the perimeter obtained changed depending on the method used, taking into account typical scientific precision and tolerances, which were well understood and accepted by those skilled in the art.

It followed that the ground for opposition according to Article 100(b) EPC did not prejudice the maintenance of the patent as granted.

Reasons for the Decision

1. The appeal is admissible.
2. The invention as claimed in claim 1 concerns a dry powder inhalation system in which the medicament to be

inhaled is kept in a closed container, e.g. a capsule, until the inhalation is to take place. Just before inhalation, the container is pierced on two opposite sides, in order to permit a flow of air through it and transport the medicament to a mouthpiece.

The core of the invention is the combination of the material of the capsule, which is claimed to be hydroxypropylmethylcellulose (HPMC) and the dimensions of the elements for piercing.

According to the specification, HPMC was a recently developed "edible" material for producing rigid swallowable capsules often used to administer powder medicaments orally. Compared to standard gelatin capsules, if pierced with piercing members of the claimed dimensions, HPMC capsules showed an improved lung deposition of the medicament, which rendered the inhalation treatment more effective.

3. *Ground for opposition according to Article 100(b) EPC*

3.1 *Admittance into the proceedings*

The Opposition Division based its decision to revoke the patent on the ground for opposition according to Article 100(b) EPC. In particular, it held that the term "the equivalent diameter of the hole or holes pierced by each piercing system" recited in claim 1 constituted an unusual parameter and that the specification did not provide sufficient information enabling the skilled person to determine it reliably.

As the appellant submits, this ground was raised after the time period specified in Article 99(1) EPC had elapsed. For this reason, the Opposition Division

should not have admitted it into the proceedings.

However, in view of Article 114(1) EPC in conjunction with decision G 10/91, it is left to the opposition divisions' discretion to admit any late-filed grounds for opposition. In exercising their discretion, they must examine those grounds as to their relevance and then admit them only if, *prima facie*, there are reasons to suspect that they prejudice the maintenance of the European patent. According to the established jurisprudence of the boards of appeal (as cited in Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.C.1.3.3), the way such discretion was exercised should only be overruled if it was done according to wrong principles, or without taking into account the right principles, or in an unreasonable way.

It is not excluded that, after a deeper analysis as to the substance of the objections based on the admitted grounds, it is concluded that they did actually not prejudice the maintenance of the European patent. However, this is irrelevant for the purpose of the previous matter of whether to admit them, which is to be done on a *prima-facie* basis.

In the impugned decision, when admitting the ground in question, the Opposition Division explained why it considered it "*prima facie* relevant" (point 2 of the decision). It even went on to revoke the patent based on that ground, which also shows how relevant the ground was in its opinion.

Hence, the Opposition Division took into account the right principles in a reasonable way.

The appellant further argued that it was not given enough time to prepare arguments and evidence to bring forward during the oral proceedings before the Opposition Division. Hence, for this reason too, the Opposition Division had been wrong in admitting the ground in question.

However, the Board notes that the appellant, after having been made aware of the objection based on the ground for opposition according to Article 100(b) EPC before the oral proceedings, already replied to the objection in writing in advance of the oral proceedings. Moreover, it did also not ask for any additional time, i.e. a postponement of the oral proceedings. Hence, the appellant's argument is not convincing.

For these reasons the Board concludes that the ground for opposition according to Article 100(b) EPC was correctly admitted into the proceedings.

3.2 *Substantive analysis*

It has to be assessed whether the skilled person, on the basis of the disclosure of the patent and its common general knowledge, could make holes having an "equivalent diameter" as claimed in claim 1 without an undue burden. In other words, it boils down to establishing whether the skilled person would understand how to determine "the equivalent diameter of a hole" within the meaning of the patent in suit.

As the Opposition Division explained in the impugned decision, the patent explicitly teaches how to determine the equivalent diameter of a piercing pin (page 4, lines 16 to 21), but not of a pierced hole.

However, in the Board's opinion, this teaching is given in connection with a section of the pin. More particularly, in the sentence on page 4, line 17 it is stated that the "equivalent diameter [...] is determined **at** [...] a section of the pin" and the following sentence refers to "the equivalent diameter **of** said section" (emphasis added). In other words, in order to determine the equivalent diameter of a piercing pin, the patent teaches that a certain cross section of that pin is to be considered first.

The patent goes on to teach how to determine the equivalent diameter of that cross section, based on the determination of its area and its perimeter, namely four times the area of the cross section divided by the perimeter.

This provides the skilled person with an implicit teaching to determine the equivalent diameter of any planar section.

The fact that the equivalent diameter of the piercing pin is generally taught to be the equivalent diameter of its cross section provides the skilled person with an implicit teaching that the equivalent diameter of an elongate three-dimensional object must be determined at a cross section of it, transverse to its longitudinal axis. In line with this teaching of the description, claim 1 requires that the equivalent diameter of the container to be pierced be determined in a cross section of the container "located in a plane perpendicular to an axis extending between the end portions".

Similarly, the skilled person willing to understand

would realise that the equivalent diameter of a hole pierced by such a longitudinal object can only mean the equivalent diameter, according to the same definition as above, of the cross section of a fictional cylinder, within the meaning of its most general geometric definition, extending along the perforation axis and having as directrix the perimeter of the hole. The Board sees no room for other technically reasonable interpretations. It is also noted that, in view of this definition, it is irrelevant whether the hole in the container may slightly shrink immediately after removal of the piercing pin, since the equivalent diameter in question is not determined on the basis of the diameter of the piercing pin, but can be directly measured at the hole.

As regards the Opposition Division's argument in the impugned decision that even the determination of the cross section of the holes and its perimeter would be technically difficult and would require "very specific and elaborate detecting and assessment means", the Board shares the appellant's view that the skilled person is aware of several methods for precisely determining the area and the perimeter of a two-dimensional object. For example, computer-implemented techniques of optical recognition could be used. It is agreed that such techniques may involve more or less complicated equipment, e.g. more or less precise optical detectors. However, what is decisive is that such equipment is at the skilled person's disposal. As long as that is the case, the degree of complexity is not relevant.

Therefore, the Board concludes that the skilled person could make holes with an equivalent diameter as claimed in claim 1 without an undue burden.

In the impugned decision the Opposition Division did not identify any other problematic claimed feature in view of Article 100(b) EPC. The Board does not see any either.

Hence, it is concluded that the invention as claimed in the patent as granted is sufficiently disclosed for it to be carried out by a person skilled in the art.

- 3.3 It follows that the ground for opposition according to Article 100(b) EPC does not prejudice the maintenance of the patent.

4. Under Article 111(1) EPC, the Board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. In view of the fact that the impugned decision did not deal with any ground for opposition other than that under Article 100(b) EPC, and that a party should normally have the opportunity to have its case examined by two instances, the Board decides to remit the case.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated