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**Datasheet for the decision
of 8 April 2022**

Case Number: T 2671/19 - 3.3.07

Application Number: 05075341.7

Publication Number: 1586311

IPC: A61K9/16

Language of the proceedings: EN

Title of invention:

Melt extrusion of spherical multiparticulates

Patent Proprietor:

EURO-CELTIQUE S.A.

Opponent:

Leistritz Extrusionstechnik GmbH

Headword:

Melt extrusion/EURO-CELTIQUE

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

Novelty - main request (no) - implicit disclosure

Inventive step - auxiliary request (no) - obvious modification

Decisions cited:

T 0153/85



Beschwerdekammern

Boards of Appeal

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Case Number: T 2671/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 8 April 2022

Appellant: Leistritz Extrusionstechnik GmbH
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 15 July 2019
rejecting the opposition filed against European
patent No. 1586311 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: M. Steendijk
L. Basterreix

Summary of Facts and Submissions

- I. European patent 1 586 311 ("the patent") was granted on the basis of four claims.

Independent claim 1 as granted related to:

"A process for preparing a controlled release pharmaceutical extrudate using a melt extruder, wherein the melt extruder comprises a die-head supporting a die-plate in which orifices are located, and a cutter adjacent to the die-head, and wherein the cutter cuts the extruded mix as it emerges under pressure and still molten from the orifices of the die-plate, wherein a stream of air of reduced temperature is directed into the region of the surface of the die-head during cutting and the rate of extrusion and the speed of the cutter blade are adjusted to give spherical shaped multiparticulates."

- II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step and that the claimed invention was not sufficiently disclosed.

The appeal was filed by the opponent (appellant) against the decision of the opposition division to reject the opposition.

- III. In the decision the opposition division cited *inter alia* the following documents:

D6 : Powerpoint-Presentation Mr Alexander Koschmider at the "Pharma Workshop 2003",

D7 : Brochure "Micro Pelletizer Serie - Technische Daten LMP 18 PH / LMP 27 PH" April 2003

D16: Expert Declaration by Treena Nicoll, 29 June 2018

IV. The opposition division came to the following conclusions:

- (a) The claimed invention was sufficiently disclosed in the patent.
- (b) The evidence relied upon by the opponent, including documents D6 and D7, did not prove that the process as defined in the patent was anticipated by the prior art. The cited documents reported that the extruder machines Leistritz Micro 18 PH and Micro 27 PH, which were also explicitly mentioned in the patent, were suitable for producing spherical extrudates containing pharmaceutical agents, but did not reveal the feature of a stream of air of reduced temperature being directed into the region of the surface of the die-head during cutting.

The subject-matter of the claims as granted was therefore new over the prior art.

- (c) Document D6 represented the closest prior art. The effect of the differentiating feature, *i.e.* the stream of air of reduced temperature directed into the region of the surface of the die-head during cutting, was the obtention of spherical particles without the problem of smearing. The skilled person would be aware of the smearing problem and the effect of the defined air stream was credible in view of the examples of the patent. The problem to be solved could be formulated as how to provide an improved process in which the tackiness of

spherical particles obtained by extrusion is reduced.

No prior art suggested directing a stream of cooling air into the region of the surface of the die-head as solution. The claimed subject-matter therefore involved an inventive step.

- V. With the reply to the statement setting out the grounds of appeal the patent proprietor (respondent) filed an auxiliary request relating to an amended set of claims.

Claim 1 of this auxiliary request defines with respect to claim 1 as granted the following additional feature:

"and wherein the outer surface of the die-head is coated with a non-stick material."

- VI. A communication pursuant to Article 15(1) RPBA was issued on 24 June 2021.

Oral proceedings were held on 8 April 2022 by videoconference.

- VII. The arguments of the appellant relevant to the present decision are summarized as follows:

- (a) Novelty (claim 1 as granted)

Document D6 disclosed an extrusion process to produce spherical particles for pharmaceutical formulations using the Leistritz Micro Pelletizer LMP 27 PH, in which the extrudate is cut as it emerges from the die-plate and is thus still in a molten state. Document D6 anticipated the subject-

matter of claim 1 as granted taking account of document D7, which described details of the LMP 27 PH extruder, including the cooling of granulates by a circulating stream of air in which the granulates are carried off.

(b) Inventive step (claim 1 auxiliary request)

The only difference between the subject-matter of claim 1 of the auxiliary request and document D6 concerned the definition of the outer surface of the die-head being coated with a non-stick material. The patent did not indicate any particular effect to result from this feature. In as far as this feature was considered to provide a solution to the problem of reducing the smearing of the molten extrudate, it was obvious to the skilled person, who was well aware of the general utility of non-stick coatings.

VIII. The arguments of the respondent relevant to the present decision are summarized as follows:

(a) Novelty (claim 1 as granted)

Document D6 did not disclose a process involving adjustment of the rate of extrusion and the speed of the cutter blade to provide spherical particles. The provenance of the particles presented in document D6 was not evident. Moreover, it was known in the prior art, in particular document D11, that the spherical shape of particles may result from subsequently applied coatings.

Document D6 did also not disclose that the extruded mix is cut as it emerges still molten from the die-

head nor that a stream of air of reduced temperature is directed into the region of the surface of the die-head during cutting. Having regard to the established jurisprudence, in particular following T 153/85, document D7 could not be relied upon to supplement the teaching of document D6 regarding these missing features. Even if the information in document D7 were taken into consideration, this document did not disclose the feature concerning the direction of the stream of air as defined in claim 1 as granted.

(b) Inventive step (claim 1 auxiliary request)

As confirmed by document D16 the coating of the surface of the die-head with a non-stick material reduced the smearing of the extrudate at the die-head. The problem of smearing was inherently addressed in the patent by the mention of the non-stick nature of the coating material. As solution to the problem of smearing the provision of the non-stick coating was not obvious from the prior art. Without any mention of non-stick coatings for an extruder die-head in the prior art and without any evidence of common knowledge regarding the application of non-stick coatings in the relevant field the skilled person could only have arrived at the claimed invention with the benefit of impermissible hind-sight.

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

- X. The respondent requested that the appeal be dismissed and the patent be maintained as granted (main request), or alternatively that the patent be maintained on the

basis of the auxiliary request filed during first instance proceedings on 2 July 2018 and resubmitted with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

Main request

1. Novelty
 - 1.1 The Board adheres to the following feature analysis presented in the decision under appeal:
 - a) A process for preparing a controlled release pharmaceutical extrudate using a melt extruder,
 - b) wherein the melt extruder comprises a die-head supporting a die-plate in which orifices are located,
 - c) and cutter adjacent to the die-head,
 - d) and wherein the cutter cuts the extruded mix as it emerges under pressure and still molten from the orifices of the die-plate,
 - e) wherein a stream of air of reduced temperature is directed into the region of the surface of the die-head during cutting and
 - f) the rate of extrusion and the speed of the cutter blade are adjusted to give spherical shaped multiparticulates.
 - 1.2 As observed in the decision under appeal (see page 8, sections 6.3 and 6.4) document D6 represents the slides of a presentation held by Mr. Koschmieder during a conference in Nurenberg in 2003 and document D7 represents the content of a brochure with a credible

publication date of April 2003, which provides information on machinery referred to in document D6. The status of documents D6 and D7 as prior art under Article 54(2) EPC has not been contested by the respondent.

- 1.3 Document D6 discloses the use of the Leistritz Micro Pelletizer LMP 27 PH for the preparation of pharmaceutical compositions in the form of spherical pellets (see slides 17 and 22-28).

As concluded in the decision under appeal (see page 8, section 6.3) the **features a), b) and c)** of claim 1 as granted are inherent in the use of an extrusion process implied by the use of the LMP 27 PH pelletizer described in document D6. This finding regarding the features a) to c) of claim 1 as granted has not been contested by the respondent during the appeal proceedings.

Document D7 represents a brochure which provides technical information regarding the Leistritz Micro Pelletizers LMP 18 PH and LMP 27 PH. According to document D7 these pelletizers are equipped with rotating blades positioned directly above the die-plate, which cut the emerging extrudate (see D7, page 2, bottom figures). When the extrudate is cut by rotating blades positioned directly above the die-plate to form spherical particles, the extrudate is inevitably still in the molten state to allow its exit from the die-head and the reported formation of spherical particles. Moreover the obtention of spherical rather than elongated particles necessarily requires that the extrusion rate and the speed of the cutter blade have been appropriately adjusted. The presented use of the LMP 27 PH pelletizer in document

D6 (see slide 22) and the display of the spherical grains obtained with this machine (see slide 25) therefore also implicitly disclose the **features d) and f)** of claim 1 as granted.

Claim 1 as granted merely defines with feature e) that "a stream of air of reduced temperature is directed **into the region of the surface of the die-head** during cutting" (highlighting by the Board). This definition regarding the direction of the air stream does not require that the air stream is actually directed in some angle towards the surface of the die-head.

Document D7 mentions that the LMP 18 PH and LMP 27 PH pelletizer avoid contacting the products with water as in conventional strand granulation by making use of a circular air stream to cool and carry off the pellets (see page 2 first paragraph). Document D7 further reveals that the cutting chamber equipped with an air inlet is connected to the die-head (see page 2 top figures). Taking account of the positioning of the cutting chamber, which is connected to the die-head, the described transporting function of the cooling air stream requires that this air stream is at least directed at the region of the surface of the die-head, be it not towards the die-head, in order to carry off the granulate. Accordingly, the use of the LMP 27 PH pelletizer described in document D6 also implicitly discloses **feature e)** of claim 1 as granted.

- 1.4 The respondent argued that in the assessment of novelty of the claimed subject-matter with respect to the teaching of document D6 the content of document D7 should not be considered having regard to the jurisprudence as established in T 153/85.

According to T 153/85 it is not permissible to "combine" separate items of prior art together for the assessment of novelty, but in case a primary document specifically refers to a second document, the presence of such specific reference may necessitate that part or all of the disclosure of the second document be considered as part of the disclosure of the primary document (see T 153/85, reasons for the decision, point 4.2, paragraph 3; see also Guidelines for Examination in the EPO, March 2022, G-IV.8).

The Board acknowledges that document D6 does not specifically refer to document D7, which explains the details concerning the LMP 27 PH pelletizer used according to document D6, in particular the position of the cutter and the cooling airstream for carrying off the granulate. However, the assessment in section 1.3 above does not "combine" the teaching of documents D6 and D7 to fill a gap in the teaching of document D6, but merely refers to the content of document D7 to establish what was, as a matter of fact, implicitly disclosed in document D6 by the reference to the use of the LMP 27 PH pelletizer for the preparation of the pharmaceutical compositions in the form of spherical pellets.

- 1.5 The Board therefore concludes that the subject-matter of claim 1 as granted lacks novelty.

Auxiliary request

2. Inventive step

- 2.1 Claim 1 of the auxiliary request additionally defines with respect to claim 1 of the main request the coating of the outer surface of the die-head with a non-stick

material. Following the conclusion regarding the main request the difference between the subject-matter defined in claim 1 of the auxiliary request and the disclosure in document D6 only concerns the definition of the non-stick coating.

- 2.2 As explained in the declaration in document D16 (see page 3, section 3.2, "Question 2"), the skilled person is faced with the problem of smearing of the pellets at the die-head when pharmaceutical extrudates are cut in the molten state on exit from the die-head.

The Board acknowledges that from the mention in the patent of the coating of the die-head with a non-stick material such as polytetrafluoroethylene (PTFE) (see paragraph [0007]) the skilled person immediately derives the purpose of the coating, namely the prevention of molten extrudate sticking to the die-head. It is therefore reasonable to conclude on the basis of the teaching of the patent that, as confirmed in document D16, the non-stick coating is suitable to reduce residual smearing and agglomeration of the extrudate.

The problem to be solved may therefore appropriately be formulated as the provision of an improved process for the preparation of spherical shaped particles.

- 2.3 The Board observes that the versatility of coatings of non-stick material such as PTFE was well known in the art. The skilled person who is confronted with residual smearing of the pellets when cutting a molten extrudate to produce spherical particles for pharmaceutical formulations as described in document D6 will therefore as a matter of obviousness consider the application of a non-stick coating to prevent the molten extrudate

from sticking to the die-head and thereby reduce residual smearing.

The respondents have not denied the well known versatility of coatings of non-stick material, but argued that in the absence of evidence of the utility of such coatings in the field of extrusion machinery an inventive step of the claimed process could only be denied on the basis of hind-sight. The Board does not consider this argument convincing, because the well known versatility of non-stick coatings already implies the general utility in preventing smearing, including in extrusion machinery in which such smearing may obviously pose a problem when the extrudate is cut in the still molten state.

- 2.4 The Board therefore concludes that the subject-matter of claim 1 of the auxiliary request lacks an inventive step.

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:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated