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**Datasheet for the decision
of 20 October 2017**

Case Number: T 0255/16 - 3.2.07

Application Number: 02706431.0

Publication Number: 1385779

IPC: B67D5/42

Language of the proceedings: EN

Title of invention:

ACCURATE DOSING PUMP AND ACCESSORIES THEREFOR

Patent Proprietor:

Cohen, Ben Z.

Opponent:

GLAXO GROUP LIMITED

Headword:

Relevant legal provisions:

EPC Art. 123(2), 84

RPBA Art. 12(4)

Keyword:

Late-filed request - admitted (yes)

Amendments (main and first auxiliary request) - added subject-matter (yes); (second auxiliary request) - added subject-matter (no)

Claim 1 of the second auxiliary request - clarity (yes)

Remittal to the department of first instance - (yes)

Decisions cited:

T 0667/08, T 0698/94, T 1123/04

Catchword:



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Case Number: T 0255/16 - 3.2.07

D E C I S I O N
of Technical Board of Appeal 3.2.07
of 20 October 2017

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 4 December 2015
revoking European patent No. 1385779 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman K. Poalas
Members: V. Bevilacqua
C. Brandt

Summary of Facts and Submissions

- I. The patent proprietor lodged an appeal against the decision of the opposition division to revoke European patent No. 1 385 779.

Opposition was filed against the patent as a whole, based on Article 100(a) EPC (lack of novelty and lack of inventive step).

- II. The opposition division's decision stated *inter alia* that claim 1 of the second and third auxiliary requests did not comply with the requirements of Article 123(2) EPC.

- III. With its letter dated 12 October 2017 the appellant requested that the impugned decision be set aside, that the board should consider the claims of the main request filed with said letter as meeting the requirements of Article 123(2) EPC and then remit the case to the opposition division for further prosecution (main request), or alternatively that the board should consider the claims of the first auxiliary request filed with said letter as meeting the requirements of Article 123(2) EPC and then remit the case to the opposition division for further prosecution (first auxiliary request), or alternatively that the board should consider the claims of the second auxiliary request filed with said letter as meeting the requirements of Article 123(2) EPC and then remit the case to the opposition division for further prosecution (second auxiliary request), or alternatively that the board should consider the claims of the third auxiliary request filed with said letter as meeting the requirements of Article 123(2) EPC and then remit the

case to the opposition division for further prosecution (third auxiliary request).

With the same letter the appellant submitted the following two documents as evidence of the knowledge of a skilled person:

D11: printout from the website www.balltecballs.com

D12: printout from the website www.ibls.com

and asked for a decision based on the written procedure.

IV. In its reply to the grounds of appeal the respondent (opponent) requested that the appeal be dismissed. Together with said reply it submitted an extract from Wikipedia (D10) as proof of the knowledge of a skilled person.

V. Oral proceedings before the board were held on 20 October 2017 in the absence of the duly summoned parties.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, proceedings were continued without the parties.

The present decision was announced at the end of oral proceedings.

VI. The wording of claim 1 of the **main request** reads as follows (amendments over the patent as granted are struck through or in bold, emphasis added by the board):

"A **micro dosing** pump (100, 200) for administering **micro** doses of **ophthalmic** fluid, **i.e. doses of 5 microliter - 50 microliter**, said pump comprising:

a reservoir (112, 214) formed to accommodate at least one of the doses of fluid;

a fluid-collecting chamber (114, 216) in communication with said reservoir, **which fluid-collecting chamber (114) defines a piston seat (116) having a dose-control portion (118), which dose control portion terminates in an end portion (120) that defines a discharge aperture (122);**

a piston (126, 218) disposed to reversibly slide within at least a **the** dose-control portion (118, 224) of said fluid-collecting chamber,

wherein, ~~upon~~ **with** actuation of the pump, said piston seals or substantially seals said dose-control portion from other portions of said fluid-collecting chamber with said piston sliding within said dose-control portion, and wherein said piston being configured to displace a volume of fluid from said sealed or substantially sealed dose-control portion which is approximately equal to ~~or greater than~~ the volume of one of the doses of fluid; and

a nozzle (142, 226), wherein said nozzle being located such that fluid displaced by said piston from said dose-control portion is generally urged towards said nozzle,

a regulator (138) disposed between said dose-control portion (118) and said nozzle (142) to selectively control flow therebetween, which regulator is in a rest position biased against the discharge aperture (122), such that it allows a one way flow from the fluid collection chamber (114),

characterized in that

with the pump (100, 200) being in a ~~quiescent~~ **rest** state, said piston (126, 218) not sealing or substantially sealing said dose-control portion (118, 224) from other portions of said fluid-collecting

chamber (114, 216) so as to allow said dose-control portion to be re-charged with fluid, **wherein during actuation, the piston (126) is urged into the dose-control portion (118) thus sealing or substantially sealing the dose-control portion (118) from other portions of the fluid-collecting chamber (114) and allowing for a pressure rise in the fluid entrapped in the dose-control portion (118), wherein with further movement of the piston (126) into the dose-control portion (118), the pressure of the fluid rises sufficiently to overcome the biasing force of the regulator, and the regulator (138) yields to allow at least a portion of the entrapped fluid to escape the dose-control portion (118) via the discharge aperture (122), and thus to exit the pump (100) and the discharge nozzle (142), and wherein the pump furthermore comprises a spring handle or return spring acting against the piston that, after actuation, returns the piston to its rest position.**

Claim 1 of the **first auxiliary request** comprises the following features added at the end of the characterising portion of claim 1 of the main request:

"and wherein said reservoir (112, 214) is vented ambiently."

The wording of the characterising portion of claim 1 of the **second auxiliary request** corresponds to that of claim 1 of the main request, with the wording of the preamble of claim 1 of the **second auxiliary request** reading as follows (the features added in respect of claim 1 of the main request are in bold, emphasis added by the board):

"A micro dosing pump (100, 200) for administering micro doses of ophthalmic fluid, i.e. doses of 5 microliter - 50 microliter, said pump comprising:

a reservoir (112, 214) formed to accommodate at least one of the doses of fluid;

a fluid-collecting chamber (114, 216) in communication with said reservoir, which fluid-collecting chamber (114) defines a piston seat (116) having a dose-control portion (118), which dose control portion terminates in an end portion (120) that defines a discharge aperture (122) **and which dose-control portion (118) is in fluid communication with a discharge chamber (134) via the discharge aperture (122) and a tapered throat (136) which diverges from the discharge aperture (122) towards the discharge chamber (134);**

a piston (126, 218) disposed to reversibly slide within at least the dose-control portion (118, 224) of said fluid-collecting chamber,

wherein, with actuation of the pump, said piston seals or substantially seals said dose-control portion from other portions of said fluid-collecting chamber with said piston sliding within said dose-control portion, and wherein said piston being configured to displace a volume of fluid from said sealed or substantially sealed dose-control portion which is approximately equal to the volume of one of the doses of fluid; and a nozzle (142, 226), wherein said nozzle being located such that fluid displaced by said piston from said dose-control portion is generally urged towards said nozzle,

a regulator (138) disposed between said dose-control portion (118) and said nozzle (142) to selectively control flow therebetween, which regulator is in a rest position biased against **the tapered throat (136) that diverges from** the discharge aperture (122) such, that

the regulator ~~it~~ allows a one way flow from the fluid collection chamber (114)"

Claim 1 of the **third auxiliary request** comprises the following features added at the end of the characterising portion of claim 1 of the second auxiliary request:

"and wherein said reservoir (112, 214) is vented ambiently."

VII. In the present case, PCT publication WO 02/068317 is considered as representing the originally filed application.

VIII. Insofar as is relevant to the present decision, the appellant argues substantially as follows:

The asserted lack of compliance of the subject-matter of claims 1 of the main and first auxiliary requests is ill-founded and not sufficiently reasoned.

The EPC does not require a literal basis for amendments to comply with the requirements of Article 123(2) EPC (T 667/08).

The term "discharge aperture" has to be understood as a skilled person would do, namely as including the area around its opening, and therefore as encompassing the tapered throat.

The tapered throat is clearly a non-essential feature of the regulator, because (as clearly shown in D11 and D12) a skilled person knows that such a device can be built without a tapered throat. The tapered throat can

therefore be omitted from the claims without adding subject-matter.

The application as filed (see Figures 2-4, page 3, last paragraph, and page 5, first paragraph) discloses that the regulator's function in its rest position is to close the discharge aperture. This implies that the regulator is biased against the discharge aperture.

A basis for claiming a micro dosing pump for delivering a dose of 5 microliter – 50 microliter is to be found on pages 1 and 14 of the originally filed description.

The feature "micro dosing pump" is clear to a skilled reader, as it is a pump for delivering doses of 5 microliter – 50 microliter.

The feature "spring handle" also does not introduce obscurities into the claims, as it refers to a handle biasing the piston into its rest position.

IX. Insofar as is relevant to the present decision, the respondent argues essentially as follows.

D10 is submitted in response to the appellant's argument that the omission of the "tapered throat" from the claims is allowable as it is not an essential feature of the originally disclosed first embodiment.

The tapered throat cannot be considered as a portion or an element of the discharge aperture.

The tapered throat is an essential feature of the originally disclosed ball check valve (see page 5, lines 3-5) because the interior surface of the discharge aperture is conically tapered to guide the

ball into the seat, thereby providing a positive seal for prohibiting any reverse flow.

T 667/08 does not provide any basis for regarding as allowable an amendment which is not derivable from the originally filed documents.

Claim 1 of the main request and of the first auxiliary request further contravenes the requirements of Article 123(2) EPC because there is no explicit or implicit disclosure of a micro dosing pump in the application as filed.

Furthermore, the application as filed makes no explicit or implicit disclosure of a pump for delivering doses of 5 microliter – 50 microliter, as the only pump capable of delivering such a dose size is described as belonging to the prior art.

The expression "micro dosing pump" is unclear, because a skilled person is not able to understand if pumps which are capable of delivering doses outside the claimed range would fall within the scope of the claim.

The feature "spring handle" is also unclear because it could refer to a handle capable of elastically biasing the piston to its rest position, but also be construed as a handle comprising a spring.

As these features are in the subject-matter of claim 1 of the second and third auxiliary requests, these requests are not *prima facie* allowable, and should not be admitted into the appeal proceedings.

The second and third auxiliary requests should also not be admitted into the appeal proceedings, as they should

have been filed during the opposition proceedings. This is because the above objections of added subject-matter and clarity were submitted by the respondent with its letter of 25 September 2015 prior to the oral proceedings before the opposition division.

As the appellant did not react in writing and did not attend oral proceedings before the opposition division, the opposition division was prevented from dealing with these requests.

Reasons for the Decision

1. *Lack of reasoning in the impugned decision.*

1.1 The appellant argues that no sufficient reasoning has been presented in the impugned decision concerning the opposition division's conclusion that the subject-matter of claims 1 of the present main and first auxiliary requests, said requests corresponding to the then second and third auxiliary requests, contravene the requirements of Article 123(2) EPC.

1.2 The board disagrees.

The appealed decision points out that the feature of a regulator being "biased against the discharge aperture", when in a rest position, has been introduced into claims 1 of the main and first auxiliary requests. It is noted in this respect that the originally filed application refers only to a regulator which is "biased against the tapered throat", when in a rest position (reference is made in this respect to paragraph [15] of the patent, corresponding to the first paragraph on page 5 of WO 02/068317). The opposition division

concluded from the above that the pump according to claims 1 of the main and first auxiliary requests claimed an originally undisclosed regulator. As a consequence, said claims 1 related to an undisclosed embodiment.

According to the Case Law of the Boards of Appeal, 8th edition 2016, III.K.4.2.1, a decision is reasoned within the meaning of Rule 111(2), first sentence, EPC if it enables the appellant and the board to examine whether the decision was justified or not. The decision has to set out the logical chain of argument upon which the conclusion was based, in respect of each and every ground that was pleaded and substantiated (T 698/94 of 17 February 1997). It should not be necessary for the board of appeal to have to reconstruct or even speculate as to the possible reasons for a negative decision in the first-instance proceedings (T 1123/04 of 25 August 2006).

The impugned reasoning of the opposition division complies with these principles set out in the case law of the boards of appeal for the following reasons:

The amendments in claims 1 of the main and first auxiliary requests held by the opposition division to contravene Article 123(2) EPC were submitted during the first-instance proceedings in claims 1 of the then second and third auxiliary requests filed with letter dated 28 August 2015. According to the case law of the boards of appeal, when filing amended claims in opposition (appeal) proceedings the amendments made have to be substantiated as to their basis in the patent application, as to which objections are to be overcome by the amendments and hence as to why the

amendments should be regarded as admissible and allowable.

The appellant's letter dated 28 August 2015 does not contain any argument, reasoning, substantiation or even any submission directed to the amendment "regulator being biased against the discharge aperture, when in a rest position". Only in the statement setting out the grounds of appeal (points 2.3 and 2.4) did the appellant submit arguments and grounds why in his view said amendment should be regarded as complying with the requirements of Article 123(2) EPC. The opposition division when taking the contested decision was therefore not even able to consider "each and every ground that was pleaded and substantiated", simply because any substantiation supporting the amendments introduced in claims 1 was missing at that time. For its reasoning to be held to comply with the requirements of Rule 111(2) EPC the opposition division could therefore not be expected to deal with all the appellant's arguments, which were only submitted after the decision had been taken. Rather, it is not objectionable under Rule 111(2) EPC that the opposition division in the absence of any substantiation for the amendments in the appellant's letter dated 28 August 2015 based its reasoning on features which in its assessment were clearly and unambiguously disclosed or, respectively, not disclosed in the originally filed application.

The board and the person skilled in the art were therefore in a position to examine whether the impugned decision is justified, considering that the decision sets out a logical argument upon which the opposition division based its conclusion without having to reconstruct or even speculate as to the possible

reasons. Therefore, taking into account the case law of the boards of appeal set out above, the board holds that the contested reasoning in the opposition division's decision does not contradict the requirements for sufficient reasoning according to Rule 111(2) EPC, even if the reasoning might be regarded as comparatively brief.

For the above reasons the board considers that the impugned decision is a reasoned decision within the meaning of Rule 111(2), first sentence, EPC.

2. *Admissibility of D10-D12*

None of the parties requested that documents D10-D12 not be admitted into the appeal proceedings.

The board likewise sees no reason not to admit these documents into the appeal proceedings.

Documents D10-D12 are therefore admitted into the proceedings.

3. *Main request, first auxiliary request - Article 123(2) EPC*

3.1 *Regulator issue*

3.1.1 The only regulator mentioned in the originally filed application belongs to the first embodiment (see figures 1-8, figures 9-17 and the last three lines of the second paragraph on page 12) and is described on pages 3 and 5 as being biased against a feature of said embodiment marked "tapered throat" and explicitly defined as diverging from the discharge aperture.

As argued by the respondent, the tapered throat is an essential feature of the originally disclosed ball check valve, because according to page 5, lines 3-5, its conical shape guides the ball into the seat and forms a positive seal prohibiting any reverse flow.

Claims 1 of the main and first auxiliary requests are directed towards a pump which does not necessarily comprise such a tapered throat diverging from the discharge aperture, because the regulator is here biased against the discharge aperture.

This means that undisclosed pumps are now claimed in which, for example, there is no tapered throat, or the tapered throat converges from the discharge aperture, or the regulator is positioned between a tapered throat and the discharge aperture.

3.1.2 The appellant argues that the application as filed discloses that the regulator's function in its rest position is to close the discharge aperture and that this implies that the regulator is biased against the discharge aperture.

The board disagrees.

According to the application as filed (see Figures 2-4 and the last four lines of the second paragraph on page 3) the regulator's function in its rest position is to prevent fluid from leaking out of the pump due to the head pressure from the reservoir by sealing the tapered throat. Such a sealing effect is achieved with a pressing contact against the tapered throat.

That there is sealing against the tapered throat (by pressing contact) cannot imply that the regulator is biased against the discharge aperture.

- 3.1.3 The appellant also argues by referring to D11 and D12 that the tapered throat is a non-essential feature of the first originally disclosed embodiment, which can therefore be omitted without adding subject-matter.

The board again disagrees. Even if the skilled person is aware that there are ball valves without a tapered throat (as shown in D11 and D12), this feature is still presented in the context of the original description as an essential feature of the first embodiment because, as also discussed above, the sealing function of the regulator is achieved through a pressing contact against the conical surfaces of the tapered throat.

Were the tapered throat to be omitted, another sealing element would be needed to guarantee the proper functioning of the pump.

- 3.1.4 The appellant then argues that the term "discharge aperture" would be understood by a skilled person as including the area around its opening, and therefore also as including the tapered throat, and that for this reason the skilled reader of claims 1 of the main and first auxiliary requests is not presented with technical information which was not originally disclosed.

The board disagrees again.

According to the first two lines on page 5 of the original description, "[t]he dose control portion 118 is in fluid communication with a discharge chamber 134

via the discharge aperture 122 and a tapered throat 136 which diverges from the discharge aperture 122 towards the discharge chamber 134."

This means that the tapered throat, which diverges from the discharge aperture, is a distinct feature, and not a portion or an element of the discharge aperture.

- 3.1.5 The board concurs with the respondent's view that the *ratio decidendi* of T 667/08 is not relevant to the present case.

According to T 667/08 implicit features of the original disclosure should be taken into account when deciding on issues of added subject-matter.

However, as discussed above (see in particular points 2.2 and 2.4) there is, in the present case, no implicitly disclosed regulator which is biased against the discharge aperture.

The only regulator derivable from the application as filed is biased against a tapered throat diverging from the discharge aperture.

For the above reasons the board concurs with the grounds set out in the appealed decision for not allowing the main request and the first auxiliary request as they both contravene the requirements of Article 123(2) EPC.

3.2 *Micro-dosing issue*

- 3.2.1 The respondent argues that the original disclosure relates only to a generic pump, and that therefore the claimed micro dosing pump for administering micro doses

of ophthalmic fluid, i.e. doses of 5 microliter – 50 microliter, extends beyond the originally filed subject-matter.

The respondent also argues that the statement on page 14, lines 6-8, of the original disclosure only contains a hint to apply the principles disclosed in the design of a micro dosing pump, and that no actual pump is immediately derivable and therefore disclosed therein.

The board disagrees. This is because the respondent at least preliminarily construes the statement on page 14, lines 6-8, of the original disclosure, according to which the "principles are particularly advantageous with microdosing pumps for administering ophthalmic fluids", as a disclosure that the pumps described in this document are based on design principles which make them suitable for microdosing ophthalmic fluids.

This amounts, in the eyes of the board, to a disclosure of a micro dosing pump suitable for administering micro doses of ophthalmic fluid.

- 3.2.2 The respondent also argues that there is no evidence that a dose of 5 to 50 microliters is, in the language of the skilled person, a micro dose, and that therefore even if a micro dosing pump were to be disclosed, this range extends beyond the content of the original disclosure.

The board disagrees again. The first paragraph of page 1, dealing with the background of the invention, provides the information that microdoses range from 5 to 50 microliter.

The respondent did not contest the correctness of the above statement, but only the fact that this information is not disclosed in a part of the original disclosure which relates to the embodiments of the invention.

The board notes in this respect that as the background of the invention belongs to the prior art, this definition of microdose is known to the skilled person.

As a consequence, the range from 5 to 50 microliter does not add to the subject-matter of the claims any technical information which was not immediately derivable by a skilled reader of the originally filed documents.

4. *Admissibility of the second auxiliary request*

4.1 The respondent argues that the second auxiliary request should not be admitted into the appeal proceedings, as it is not clearly allowable due to a lack of clarity, and as it could and effectively should have been filed during the opposition proceedings.

This is because the issue of lack of compliance of the feature "biased against the discharge aperture" with the requirements of Article 123(2) EPC was raised during the opposition proceedings, and as a consequence the appellant should have reacted to it by already filing amendments during the opposition proceedings.

4.2 The board disagrees. According to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA), it lies within the discretion of the board to admit such late-filed requests into the proceedings.

The board does not consider the alleged lack of clarity to be a reason not to admit the second auxiliary request (see also point 6 of the present decision).

The fact that a particular objection was raised during the opposition proceedings (with letter of 25 September 2015, i.e. only four days before oral proceedings) is not a reason for concluding that the appellant **should** have submitted the present second auxiliary request even before the opposition division took position in the present case, on this particular issue, namely in the appealed decision.

The subject-matter of claim 1 of this request includes the feature of the regulator being in a rest position biased against the tapered throat that diverges from the discharge aperture.

This is a straightforward reaction to the non-allowance of claims 1 of the then second and third auxiliary requests in the impugned decision.

The present second auxiliary request was already filed together with the grounds of appeal.

For the above reasons, the board decides to admit the second auxiliary request into the appeal proceedings.

5. *Second auxiliary request - amendments, Article 123(2) EPC*

- 5.1 The feature of the regulator being in a rest position biased against the tapered throat that diverges from the discharge aperture has been added to the subject-matter of claim 1 of this request.

- 5.2 As a consequence, the reason for not allowing claims 1 of the main and first auxiliary requests becomes redundant.
- 5.3 The further feature added with respect to the main request is that the dose-control portion is in fluid communication with a discharge chamber via the discharge aperture and a tapered throat which diverges from the discharge aperture towards the discharge chamber.
The basis for this feature is to be found on page 5, lines 1-5, of the originally filed description.
- 5.4 As the only other objection of added subject-matter raised by the respondent (see the discussion of the "micro-dose" issue above) against features present in the claims of this request has not been followed by the board, the board sees no reason to consider that the requirements of Article 123(2) EPC are not satisfied by the second auxiliary request.
6. *Second auxiliary request - clarity, Article 84 EPC*
- 6.1 The appellant argues that the expression "micro dosing pump" is unclear to the skilled person.
- 6.2 The board disagrees, because a skilled reader of claim 1 of the second auxiliary request would immediately understand that such a micro dosing pump is a pump for delivering a micro dose comprised between 5 microliter and 50 microliter, see hereto also page 1, lines 5 to 11, and page 14, lines 6 to 8, of the originally filed application.
- 6.3 The board also considers the feature "spring handle" to be clear when read in combination with the remaining

features of claim 1 of the second auxiliary request. A skilled person would immediately understand that it refers to a handle which after actuation is capable of elastically biasing the piston to its rest position, see paragraph bridging pages 7 and 8 of the originally filed application. Such a handle or a part of it may be in the form of a spring.

6.4 For the above reasons the requirements of Article 84 EPC are met.

7. *Remittal*

7.1 The impugned decision contains a negative novelty assessment of claims 1 of the present main and first auxiliary requests, see pages 5-7 of the impugned decision.

7.2 Claim 1 of the present second auxiliary request, being directed towards a micro dosing pump comprising a regulator, contains subject-matter which substantially differs from what was examined for novelty in the impugned decision.

7.3 For this reason the board, in order to not deprive the parties of the opportunity to argue their case before two instances, considers it appropriate to remit the case to the department of first instance for further prosecution pursuant to Article 111(1) EPC.

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:



G. Nachtigall

K. Poalas

Decision electronically authenticated