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Datasheet for the decision of 17 August 2010

Case Number: T 0018/08 - 3.3.02

Application Number: 99962978.5

Publication Number: 1140273

IPC: A61M 29/02

Language of the proceedings: EN

Title of invention:
Device for locally delivering a drug in a body cavity

Patentees:
Boston Scientific Limited
St. Elizabeth's Medical Center, Inc.

Opponent:
Bayer Schering Pharma Aktiengesellschaft

Headword:
Device for drug delivery/BOSTON SCIENTIFIC

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 83

Keyword:
"Main request: Amendments - added subject-matter (yes) claimed combination of features not individualised"
"Auxiliary requests: Disclosure - sufficiency (no): feature not defined and therefore not to be measured"

Decisions cited:
-

Catchword:
-

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Case Number: T 0018/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 August 2010

Appellants: (Patent Proprietors)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 23 October 2007 revoking European patent No. 1140273 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
T. Karamanli

Summary of Facts and Submissions

I. European patent No. 1 140 273, based on international application PCT/US1999/028544 published as WO 2000/032267 and having European patent application No. 99 962 978.5, was granted with 11 claims.

Independent claim 1 as granted read as follows:

"A system for localized delivery of a therapeutic agent to a target location within a body cavity, vasculature, or tissue of a mammal, comprising:
an expandable catheter, and
a therapeutic agent which is incorporated into the expandable catheter or coated onto the surface of the expandable catheter per se or as part of a coating, characterized in that
the therapeutic agent is dissolved in a solvent as a substantially saturated solution with a concentration of the therapeutic agent in said solvent of at least 75% of the limit of solubility of the therapeutic agent in said solvent."

II. Opposition was filed against the granted patent under Article 100(a) EPC 1973 (novelty and inventive step), Article 100(b) EPC 1973 (added subject-matter) and Article 100(c) EPC 1973 (sufficiency of disclosure).

III. By its decision posted on 23 October 2007, the opposition division revoked the patent under Article 102(1) and (3) EPC 1973.

The opposition division held that the claims of the main request and of auxiliary request 1 did not meet

the requirements of Article 123(2) EPC 1973 and Article 83 EPC 1973. Auxiliary request 2 was not admitted into the proceedings.

The opposition division found that the teaching of claims 1 of the main request and of auxiliary request 1 with respect to the catheter to be used and to the way the therapeutic agent was associated to the catheter amounted to a selection out of two lists disclosed in the application as originally filed.

In addition, a catheter which was suitable for localised delivery of a dissolved therapeutic agent coated as such to the exterior of the expandable catheter was not disclosed in such a manner that the invention could be carried out by a skilled person. Moreover, the parameter "limit of solubility" was not generally known for any kind of substance.

IV. The appellants lodged an appeal against that decision and filed grounds of appeal together with a request that the patent be maintained according to their main request or their auxiliary request I or II. Claim 1 of the main request corresponds to the patent as granted. With their letter of 15 July 2010, they submitted two further sets of claims as auxiliary requests III and IV together with further documents.

V. On 17 August 2010, oral proceedings took place before the board.

During the oral proceedings, the respondent filed new auxiliary request 1 and renumbered the auxiliary requests I to IV as filed in writing as auxiliary

requests 2 to 5. New auxiliary request 1 (in the following called auxiliary request 1) was admitted into the proceedings. It contains four claims.

Claim 1 of the main request differs from claim 1 as granted in that the word "substantially" is missing before "saturated solution" and the term "limit of solubility" is replaced by "limit solubility". The claim is worded as follows (amendments to claim 1 as granted shown in bold):

"A system for localized delivery of a therapeutic agent to a target location within a body cavity, vasculature, or tissue of a mammal, comprising:
an expandable catheter, and
a therapeutic agent which is incorporated into the expandable catheter or coated onto the surface of the expandable catheter per se or as part of a coating, characterized in that
the therapeutic agent is dissolved in a solvent as a ~~**substantially**~~ saturated solution with a concentration of the therapeutic agent in said solvent of at least 75% of the limit ~~**of**~~ solubility of the therapeutic agent in said solvent."

The wording of claim 1 of auxiliary request 1 results from a combination of claims 34, 33 and 30 as originally filed together with the details describing the "substantially saturated solution" as contained in claim 1 as granted (added text with respect to claim 1 as granted shown in bold):

"A system for localized delivery of a therapeutic agent to a target location within a body cavity, vasculature, or tissue of a mammal, comprising:
a catheter, that delivers the therapeutic agent at a pressure of from about 0 to about 5 atmospheres, said catheter having a substantially saturated solution of said therapeutic agent associated therewith,
the therapeutic agent being dissolved in a solvent as a saturated solution with a concentration of the therapeutic agent in said solvent of at least 75% of the limit solubility of the therapeutic agent in said solvent,
said catheter including an expandable portion, and said expandable portion being coated with a polymer coating that includes said substantially saturated solution."

In claim 1 of auxiliary request 2 with respect to claim 1 of the main request, the term "onto the surface of the expandable catheter" is replaced by "onto the expandable portion of the expandable catheter".

In claim 1 of auxiliary request 3, with respect to claim 1 of auxiliary request 2, the words "per se or" are deleted.

In claim 1 of auxiliary request 4, with respect to claim 1 of the main request, the term "a therapeutic agent which is incorporated into the expandable catheter" is replaced by "a therapeutic agent which is held in a cavity or in cavities of the expandable catheter" and "limit of solubility" is used as in claim 1 as granted.

In claim 1 of auxiliary request 5, with respect to claim 1 of the main request, the term "a therapeutic agent which is incorporated into the expandable catheter" is replaced by "a therapeutic agent which is held in a cavity or in cavities of the expandable catheter", the term "onto the surface of the expandable catheter" is replaced by "onto the expandable portion of the expandable catheter" and the term "limit of solubility" is used as in claim 1 as granted. The claim reads as follows (amendments to claim 1 of the main request shown in bold):

"A system for localized delivery of a therapeutic agent to a target location within a body cavity, vasculature, or tissue of a mammal, comprising:
an expandable catheter, and
a therapeutic agent which is **held in a cavity or in cavities of the expandable catheter** ~~**incorporated into the expandable catheter**~~ or coated onto the ~~surface of~~ **expandable portion of** the expandable catheter per se or as part of a coating,
characterized in that
the therapeutic agent is dissolved in a solvent as a saturated solution with a concentration of the therapeutic agent in said solvent of at least 75% of the limit **of** solubility of the therapeutic agent in said solvent."

VI. The appellants' submissions may be summarised as follows:

There was no selection out of the lists containing different types of catheters on the one hand and different types of ways in which the therapeutic agent

could be associated with the expandable catheter as the medical device on the other hand, because it was clarified in the application as originally filed that expandable catheters were the main example for carrying out the invention. In addition, the last alternative for the association of the therapeutic agent as passing through the catheter was simply dropped since it was only disclosed with respect to a needle injection catheter which *per se* was no expandable catheter.

Finally, all embodiments of the invention in the form of the examples were directed to expandable catheters and there were several more passages in the application as originally filed referring to expandable catheters, in particular claim 34.

With respect to sufficiency of disclosure the appellants pointed out that the "limit of solubility" could easily be estimated by the skilled person for each therapeutic agent in a solvent, just by determining the maximum quantity of therapeutic agent that could be dissolved in a specific volume of solvent (usually while the solvent was stirred) at standard conditions. Should the meaning of this term really be unclear, this was an issue under Article 84 EPC 1973 and not open to discussion in the current case, because the passage containing the term was unamended with respect to the claims as granted.

VII. The respondent's arguments may be summarised as follows:

As far as added subject-matter was concerned, the respondent pointed out in particular that reference to claim 34 as originally filed was not possible, because

its features relating to the pressure of application were not present in claim 1 as currently requested. In addition, not all the examples referred to expandable catheters and even if they did, this fact could not supply the source for restricting claim 1 of any request to expandable catheters as the device.

With respect to sufficiency of disclosure the respondent held *inter alia* that the "limit of solubility" could not be determined. The maximum concentration of solute dissolvable in a solvent could at least not be determined without a reference to temperature.

VIII. The appellants (patentees) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the claims filed as main request with letter of 3 March 2008 or alternatively on the basis of the claims filed as auxiliary requests 1 to 5.

IX. The respondent (opponent) requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. *Admissibility of auxiliary request 1*

The amendments in this request were occasioned by the respondent's and the board's arguments during the oral proceedings.

In addition, the independent claim of this request is merely a combination of dependent claims from the application as originally filed, which have already been discussed in the proceedings before the opposition division (see decision of the opposition division, page 3, first paragraph under point 2.2 and patentees' reply to the notice of opposition, dated 3 November 2006, page 2, last but one paragraph). Thus, the amendments are clear-cut and *bona fide* attempts to answer the arguments brought forward during the oral proceedings.

The request is therefore admitted into the proceedings under Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA).

3. *Article 123(2) EPC; main request*

3.1 The wording of claim 1 of the main request differs from claim 1 as granted in that the words "substantially" before "saturated solution with a concentration and …" and "of" in the term "limit of solubility" are omitted.

3.2 The subject-matter of claim 1 of the main request, however, cannot be derived from original claim 30 as alleged by the appellants.

Original claim 30 relates to "a system … comprising a medical device that delivers the therapeutic agent at a pressure of from about 0 to about 5 atmospheres …".

The pressure-related feature contained in original claim 30 at least means that the system must be suitable for administration of the therapeutic agent in the defined range of pressure. Deleting this feature amounts to adding subject-matter to this claim since the restriction inferred to it by characterising its suitability ceases to apply.

3.3 As regards a disclosure without pressure-related features, it is to be noted that the subject-matter of claim 1 of the main request relates to three different ways of associating a substantially saturated solution of a therapeutic agent with an expandable catheter as the claimed device:

"… a therapeutic agent

- which is incorporated into the expandable catheter
- or coated onto the surface of the expandable catheter per se
- or as part of a coating …"

The comprehensive explanation of the meaning of the term "associated with" in connection with the substantially saturated solution is to be found on page 5 of the description as originally filed, lines 24 to 33:

"The substantially saturated solution is **associated with** the medical device in that the therapeutic agent

- is held in a cavity(ies) of the device, such as in an infusion style catheter such as a channel balloon catheter;
- or the therapeutic agent is coated onto the surface of the device as a coating per se

– or as part of a coating;
– or the substantially saturated solution is held within or passes through the medical device, such as in a needle injection catheter." (letters in bold by the board)

If the alternative "the substantially saturated solution is held within … the medical device" is disregarded - as was done during the proceedings till now and is continued in order to avoid further complications in the case - this comprehensive explanation contains four different ways in which a substantially saturated solution of a therapeutic agent may be associated with medical devices. The kind of devices is illustrated in the form of examples presented under the wording "such as".

"Such as" in this presentation of examples means that the forms of "association" described are not restricted to these examples, for instance the way of association mentioned under the forth bullet-point "… passes through the medical device" may relate to a "needle injection catheter" but can also relate to any other suitable catheter. Therefore, the "passes through …" way of association does not necessarily qualify as inapplicable if the device is restricted to expandable catheters and a needle injection catheter is not an expandable catheter.

Consequently, the mentioning of the three ways of association with an expandable catheter as contained in the current claim 1 of the main request, with respect to the comprehensive explanation on page 5 of the

description as originally filed, lines 24 to 33, is an arbitrary choice out of a list of possibilities.

As far as the restriction of the device to an expandable catheter itself is concerned, there are several lists of "suitable catheter[s], such as, for example" to be "used with the present invention" (see description, page 6, lines 8 and 9) or as "medical devices within the scope of the present invention" (see page 5, line 36 to page 6, line 1). The most general one of these lists on top of page 6 of the description as originally filed is introduced by "The present invention is described herein with specific reference to an expandable catheter as the medical device. Other medical devices …" (see page 5, lines 34 to 36). This introduction, however, means nothing other than that the expandable catheter is chosen in order to be used to specifically describe features of the "invention". It does not confer any state of preferred embodiment on the expandable catheter, be it literally or by consistent interpretation of the phrase.

Thus, also the restriction of the device to the expandable catheter amounts to an arbitrary choice of this specified embodiment from the teaching of the application as originally filed.

3.4 In addition, in no other part of the description is the totality of the three ways of association, together or as an agglomeration of the single ones, mentioned in context with the substantially saturated solution of the therapeutic agent and/or an expandable catheter. Either the description refers to the "expandable portion of a catheter", which is not a synonymous term

for "expandable catheter", or there is no context with a substantially saturated solution, or both of these deficiencies apply. This relates in particular to page 6, lines 8 to 21 and page 8, lines 24 to 31, parts of the application as originally filed on which the appellants relied as source of original disclosure.

3.5 Consequently, directing the subject-matter of claim 1 of the main request to its combination of three ways of association with an expandable catheter as the device results in claiming embodiments of the teaching of the application as originally filed that are not individualised there and therefore appear in sum as an arbitrary choice. The requirements of Article 123(2) EPC therefore are not met.

3.6 Under these circumstances, the additional arguments of the appellants with respect to Article 123(2) EPC cannot succeed.

A majority or all examples in an application as originally filed having one feature in common does not limit the subject-matter of a claim to this common feature and therefore is no valid basis for a corresponding restriction. Thus, all the examples being directed to expandable catheters, even if undisputed, cannot represent the source of original disclosure of expandable catheters being the only device referred to in claim 1 of the main request.

4. *Auxiliary request 1*

4.1 *Article 123(2) and (3) EPC*

4.1.1 Claim 1 of auxiliary request 1 can be derived from claims 34, 33 and 30 in combination with page 5, lines 15 to 21 of the application as originally filed.

It is restricted to the way of association of the substantially saturated solution (as explained on page 5, lines 15 to 21 of the original description and set out in claim 1 as granted) with the expandable catheter (now in terms of a "catheter including an expandable portion") that corresponds to the wording

"a therapeutic agent … coated onto the surface of the expandable catheter … as part of a coating".

Since the term "surface" in claim 1 as granted is not further specified (e.g. as inner or outer surface or something similar) the meaning of the wording "said expandable portion being coated with a polymer coating" without mentioning the word "surface" is regarded as not exceeding the teaching of claim 1 as granted.

4.1.2 Thus, claim 1 of auxiliary request 1 meets the requirements of Article 123(2) and (3) EPC.

4.2 *Auxiliary request 1; Article 83 EPC 1973*

4.2.1 Auxiliary request 1 refers to a system for localized delivery of a therapeutic agent comprising a catheter and a substantially saturated solution of said therapeutic agent in a solvent.

The substantially saturated solution of said therapeutic agent in the solvent is characterised by a minimum value above which the concentration of the therapeutic agent in said solvent is to be found.

By this means, the parameter "concentration … of at least 75% of the limit solubility …" being a concentration in relation to the limit solubility (relative concentration) is considered to deliver information necessary to describe the claimed system.

Consequently, in order to carry out the invention characterised by that parameter, the skilled person must be able to measure in a very clear and complete way the relative concentration of therapeutic agent in the substantially saturated solution contained in any one of the systems he tries to produce according to all the features set out in claim 1 of auxiliary request 1 (reproducible measurement on the same sample with the same apparatus under the same conditions) and he must be sure that the measured value is the same as the appellants obtained for their substantially saturated solution contained in their corresponding device before filing their application (repeatable measurement on another sample of the same kind with another apparatus, but under the same conditions).

4.2.2 In order to measure the relative concentration, the reference concentration "limit solubility" must be known.

"Limit solubility", however, or "limit of solubility" (as is used in claim 1 as granted) are not common terms

known in the world of the person skilled in the art. In addition, these terms are also not defined in the description as originally filed.

4.2.3 Under these circumstances it does not matter that claim 1 as granted as well as claims 1 of the current auxiliary requests 4 and 5 relate to "limit of solubility" while claims 1 of the current main request and the auxiliary requests 1, 2 and 3 contain the term "limit solubility". Each of the terms "limit of solubility" and "limit solubility" is nowhere defined and since in the description as originally filed "limit of solubility" is used in order to describe the term "substantially saturated solution" (see page 5, lines 15 to 21) and is unequivocally meant as source of disclosure for claim 1 of auxiliary requests 1, 2 and 3 too, the present decision generally uses "limit of solubility" below.

4.2.4 Since there is no definition of the term "limit of solubility" and what the skilled person would do to give it any meaning is open, the person trying to carry out the invention never knows whether a device produced by him would meet the features of claim 1 as filed under auxiliary request 1, because he can never be sure whether another skilled person would give it another meaning transferring his device from being covered by the claim to not being covered. Thus, he is not in a position to carry out the invention as described by this claim.

4.2.5 In the circumstances of the case, the arguments of the appellants with respect to Article 83 EPC 1973 cannot succeed:

The appellants' arguments result in the opinion that the person skilled in the art would automatically read "limit of solubility" as synonymous with "saturation" of a solution and refer to experiments to determine the maximum concentration of therapeutic agent in a pure solvent using standard conditions of temperature, pressure etc. and keeping pure agent and solution under equilibrium.

However, since the term is not generally defined, the skilled person could equally read "limit of solubility" as an invitation to exceed these equilibrium conditions in some way, for instance by trying to produce oversaturated solutions stable under particular conditions and taking their concentration as reference for "limit of solubility".

On the other hand, even if committing himself to equilibrium conditions the person skilled in the art could apply "limit of solubility" either with respect to the equilibrium concentration at room temperature or at the temperature at which the system was finally to be used, 37°C.

In any case, a system produced under one particular definition of "limit of solubility" could fall under the scope of the claim and equally be out of this scope under another definition.

Thus the skilled person never knows whether he is staying within the scope of the claim or not and therefore cannot purposively carry out the invention.

5. *Auxiliary requests 2 to 5; Article 83 EPC 1973*

It is clear from the argumentation under point 4.2 of this decision that the use of the undefined term "limit of solubility" results in a teaching of claim 1 that cannot be carried out in the sense of Article 83 EPC 1973.

In claims 1 of auxiliary requests 2 to 5 the term "limit of solubility" still exists and it is used in the same way as in claim 1 of auxiliary request 1. Therefore, these auxiliary requests 2 to 5 do not meet the provisions of Article 83 EPC 1973 either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald