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Datasheet for the decision of 3 November 2010

Case Number: T 0434/06 - 3.2.02

Application Number: 99302918.0

Publication Number: 0950386

IPC: A61F 2/06

Language of the proceedings: EN

Title of invention:
Stent with local rapamycin delivery

Patentee:
Cordis Corporation

Opponent:
TRE ESSE PROGETTAZIONE BIOMEDICA S.r.l.

Headword:
-

Relevant legal provisions:
EPC Art. 54(2), 56, 88(4), 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54(3), 87(1)(4), 158(1)(2)

Keyword:
"Extended subject-matter (no)"
"Validity of priority (yes)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
G 0002/98

Catchword:
-

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Case Number: T 0434/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 3 November 2010

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 17 February 2006 concerning maintenance of the European patent No. 0950386 in amended form.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
J. Geschwind

Summary of Facts and Submissions

I. By its interlocutory decision posted on 17 February 2006 the Opposition Division decided concerning maintenance of European patent No. 0 950 386 in amended form.

II. An appeal was lodged against this decision by the opponent, by notice received on 28 March 2006, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 6 June 2006.

III. By communication of 9 September 2010, the Board forwarded its provisional opinion to the parties.

IV. Oral proceedings were held on 3 November 2010.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed or, as an auxiliary request, that the decision under appeal be set aside and that the patent be maintained on the basis of either one of the sets of claims filed before the Opposition Division on 13 January 2006 as auxiliary requests 1 to 3.

V. The following documents are of importance for the present decision:

A1: EP-A-0 747 069

A9: WO-A-98/23228

A10: EP-A-0 850 604.

VI. Independent claims 1 and 7 of the main request (claims as maintained by the Opposition Division) read:

"1. A stent comprising:
a generally thin walled cylinder, said cylinder containing a plurality of struts (10, 20, 30), said struts expandable dependent on the amount of force applied to said strut, and said struts having a generally uniform thickness; and a channel (11, 21, 31) formed in at least one of said struts, said channel having a closed perimeter on three sides and an open top, and said channel smaller in all dimensions than said strut, said channel containing a therapeutic agent applied therein."

"7. A stent comprising a generally thin walled structure containing a plurality of struts (10, 20, 30), the struts expandable to assume the shape of a lumen into which the stent is emplaced, said struts having a thickness, and a channel (11, 21, 31) formed in at least one of said struts, said channel having a closed perimeter on three sides and an open top, and said channel smaller in all dimensions than said strut, said channel containing a therapeutic agent applied therein."

Claims 2 to 6 are dependent claims.

VII. The appellant's arguments are summarised as follows:

The amendments made in paragraphs [0017] and [0035] of the patent specification had no basis in the application documents as originally filed. There was no disclosure in these documents of a reservoir which was loaded with a drug without being covered by a coating or membrane of biocompatible material. Describing the invention as relating to open reservoirs (without a coating over their top) thus constituted an unallowable extension beyond the subject-matter as filed. The third paragraph on page 7 of the description as originally filed consisted of only two sentences which had to be construed together as a complement to the invention as described more generally in the previous paragraph bridging pages 6 and 7. No reasons existed why a skilled person reading these paragraphs, both belonging to the "Summary of the Invention", would understand that the alternative to the existing technology lay only in the first sentence (reservoirs alone) and not in the second sentence (coating over the reservoirs). This would also be inconsistent with the requirement of controlled release of the drug over a period of several weeks, as stated in the (intermediate) second paragraph of page 7, which could only be achieved by a coating or membrane applied over the reservoirs. Moreover, such a coating was described as advantageous in the subsequent paragraph bridging pages 7 and 8, to be considered in relation with the function of controlling the diffusive release of the drug as mentioned in the paragraph bridging pages 15 and 16. Accordingly, there was no teaching to dispense with a membrane or coating applied over the reservoirs loaded with the drug. The statement in the second paragraph on page 17 that the reservoirs

could be "open or closed as desired" could not be construed as an indication that a coating, membrane or outerlayer covering the reservoirs was not present, as control of the release of the drug was necessary.

Since the description as originally filed was identical to that of the priority document, the claimed priority was not valid either, since the amendments of paragraphs [0017] and [0035] and the resulting interpretation of the reservoirs remaining "open", i.e. uncovered, was not supported by the priority document. The claims of the priority document were quite succinct and confined to generally defining the presence of reservoirs or channels in a stent, without any further specification. It could not be derived that the invention was limited to a stent having reservoirs or channels with an open top.

Since the claimed priority was not valid, documents A9 and A10 became part of the prior art for the purpose of evaluating both novelty and inventive step. A1, A9 and A10 took away the novelty of claims 1 and 7 as granted. Also, their subject-matter did not involve an inventive step in view of A1, A9 and/or A10.

The features of claims 1 and 7 were all known from A10. In particular, the channels disclosed therein had a length shorter than the strut. The representations of the channels in Figures 5 and 6 were similar to the representation in Figure 2b of the patent in suit. If the channels of A10 were not shorter than the strut, their ends would be open, resulting in undesired "peeling off" of the therapeutic agent during introduction of the stent through the vascular system.

Furthermore, channels with open ends would be mechanically weakened upon crimping of the stent onto a balloon, also leading to a potential detachment of the agent. These disadvantageous effects were explained in a letter from two of the inventors of A10 dated 14 June 2006. Moreover, in column 3, lines 54 to 57 of A10 it was stated that sculpturing of the surface of the stent was only provided over a part of its outer surface, inevitably meaning that the channels were shorter than the whole length of the stent. The embodiments in Figures 1 to 3 would lead to micropores being smaller in all dimensions than the strut, and there was no reason why this should not be also the case for the channels of Figures 5 and 6.

Figure 10B of A1 in connection with column 20, lines 2 to 34 clearly disclosed a square-shaped well or channel having a closed perimeter on three sides and an open top as claimed. Moreover, claims 1 and 7 at issue did not exclude the claimed stent being an intermediate product. Since the bioactive material disclosed in A1 had necessarily to be placed in the channels before the porous layer was coated on the stent, the intermediate product obtained when the porous layer was not (yet) applied fell under the wording of the claims. Furthermore, in case of a very thin porous layer, the channels could still be regarded as having an "open top", even in a state when the layer was applied.

The patent in suit taught that applying a coating was advantageous, but was entirely silent with respect to any advantages that could be achieved by omitting the coating. However, an invention "by-way-of-omission" should be supported by a positive teaching in this

respect if inventive step was to be acknowledged. In view of the risks of detachment of the therapeutic agent not covered by a coating during insertion of the stent and its expansion, the claimed stent was in fact an "unfulfilled dream". The claimed invention had actually been made retrospectively and "smuggled" into the original disclosure.

Since the provision of a coating as disclosed in A1 was generally expensive, it was obvious to leave it out if not needed. The respondent's argument that even in open channels the therapeutic agent would be less exposed to getting washed off was not acceptable since more information would be needed, for instance with respect to the geometry of the channels, in order to justify the presence of an inventive step based on this effect.

VIII. The respondent's arguments are summarised as follows:

In the second sentence of the third paragraph on page 7 of the description as originally filed, the presence of a coating or membrane was clearly described as optional, and there was simply no logical reason to construe it together with the preceding sentence, as attempted by the appellant. The concept of a reservoir containing a drug without a coating or membrane was also supported by lines 13 to 14 of page 17, with the term "closed" meaning a reservoir which is closed by a coating or membrane, and the term "open" relating to a reservoir which does not have such coating or membrane.

Since the priority application contained the same description and drawings (albeit in informal form) as the application as originally filed, the claimed

priority was also valid in accordance with Article 87(1) EPC 1973. Under these circumstances, A9 and A10 did not constitute prior art for the purposes of Article 56 EPC. Moreover, A9 had not validly entered the regional phase before the European Patent Office and therefore did not constitute prior art under Article 54(3) EPC 1973.

A10 did not take away the novelty of claims 1 and 7. From the fact that Figures 5 and 6 were roughly similar to Figure 2b of the patent in suit it could not be derived that the length of the channels was shorter than the length of the strut. This was not implied by the statement of surface sculpturing being applied only "over a part" of the surface either. The embodiments of Figures 1 to 3 were completely independent from those shown in Figures 5 and 6 and their teaching could not be combined. The alleged risks of detachment of the therapeutic agent, as addressed in the letter from the inventors of A10, did not mean that the channels had to be shorter than the strut.

The term "open top" used in claims 1 and 7 had to be understood as excluding the presence of a coating/membrane/outerlayer covering the open top of the channel/reservoir. In contrast, the entire teaching of A1 related to a porous layer covering the therapeutic agent for controlling its release. The provision of a porous layer was in fact an essential feature of the invention described in A1. There was no disclosure whatsoever in A1 of channels having an open top. The appellant's alleged disclosure of an intermediate product falling under the terms of the claims in suit was artificial and isolated from the

entire teaching. The subject-matter of claims 1 and 7 was therefore novel vis-à-vis A1 as well.

Since the presence of a porous layer was essential to the invention disclosed in A1, there would be no motivation for the skilled person to modify the device of A1 by removing this porous layer, and providing channels with an open top, and to thus arrive in an obvious manner at the invention of the patent in suit. The appellant's argumentation was therefore based on hindsight. The advantages achieved by the invention as claimed could be clearly derived from the patent description.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claims 1 and 7 according to the main request correspond to claims 1 and 8 as granted, respectively. They are based on claims 1 and 8 as originally filed, respectively, with the perimeter of the channels being defined as closed on three sides, instead of on all sides as originally claimed. This amendment can be clearly derived from Figure 3b and has not been contested.

Paragraph [0017] of the specification (corresponding to the penultimate paragraph of page 7 of the description as originally filed) has been amended to clarify that the reservoirs are loaded with a drug and that a

coating or membrane of biocompatible material applied over the reservoirs is not in accordance with the invention. Paragraph [0035] of the specification (corresponding to the second paragraph of page 17 of the description as originally filed) has been amended by deleting the alternative of the reservoirs/channels being closed. These amendments were carried out during oral proceedings in opposition in order to provide consistency with the claims in the version as accepted by the Opposition Division. They clarify that the channels/reservoirs exclude the presence of a coating/membrane/outerlayer covering their open top. The appellant's objections to these amendments are not convincing for the following reasons.

From the second sentence of the third paragraph on page 7 of the description as originally filed, it is clear that a coating or membrane covering the reservoirs (corresponding to the channels as claimed) was described as optional ("could be applied"). In the preceding sentence it was stated that the reservoirs "could be loaded with the drug". Accordingly, the presence of a drug (corresponding to the term "therapeutic agent" in the claims) was also disclosed as optional. This implies the disclosure of altogether four alternatives: reservoirs with or without a drug or reservoirs with or without a coating.

With the amendments introduced in the corresponding passage of the patent specification, the respondent has clearly and deliberately indicated that the subject-matter of the invention as claimed in the main request is restricted to one of these four alternatives, viz. reservoirs being loaded with a drug ("channel

containing a therapeutic agent therein") and not covered with a coating ("channel having ... an open top").

Both options were originally clearly presented as separate alternatives, and there is no reason to construe the two sentences together and to require the presence of both options only simultaneously. The fact that the paragraph bridging pages 15 and 16 also mentions a polymeric outerlayer acting as a diffusion controller does not imply that its presence is essential to the invention, since control of the release of the drug can also be achieved in other ways, as will be shown below (point 5).

The second paragraph on page 17 of the original description discloses "open" and "closed" reservoirs as equal alternatives. The elimination of the second alternative ("closed"), to provide consistency with the claims as maintained by the first instance, is regarded as a normal step of adapting the description to the amended claims and cannot be construed as an extension introducing new subject-matter. In the context of the original description, the term "closed", as applied to a reservoir containing a drug, means that it is closed by some kind of a coating which controls the diffusion of the drug out of the reservoir. Conversely, a reservoir which is "open" is one which does not have such a coating. The interpretations of the term "open" attempted by the appellant as relating to the distal and/or proximal ends of the channels being open, or as the channels forming through-holes or slots in the struts, are regarded as artificial and inappropriate in

this context, since claims 1 and 7 at issue clearly specify that the channels have an open **top**.

It follows that the amended description does not comprise added subject-matter in breach of Article 123(2) EPC.

3. *Priority*

The description of the priority document (USSN 09/061568) is identical to that of the application as originally filed (the drawings of the priority document are merely presented in informal form). Since, as explained above (point 2), the appellant's objections regarding an alleged extension of subject-matter by amending the description are not justified, the same arguments cannot call into question the validity of the claimed priority either, since both applications are concerned with the same invention (Article 87(1) EPC 1973), i.e. the same subject-matter (Article 87(4) EPC 1973).

The fact that the claims of the priority document are much broader than those of the application as originally filed plays no role in the present case since the content of the claims of the priority document is not decisive with respect to the grant of priority (Article 88(4) EPC). The subject-matter of the claims of the main request can be derived directly and unambiguously from the priority document as a whole (G 2/98, headnote). In particular, the feature of the channels having a closed perimeter on three sides and an open top can be clearly derived from Figures 2b and 3b and page 17, lines 10 to 14 of the priority

document. The claimed priority is thus valid for the set of claims of the main request.

Accordingly, the claims of the main request and the description, amended accordingly, are entitled to the priority date, in compliance with the requirements of Article 87(1) EPC 1973 and Article 88(4) EPC.

4. *Novelty*

4.1 Document A9

A9 was published after the priority date of the opposed patent and therefore does not constitute prior art under Article 54(2) EPC. Furthermore, it does not constitute a state of the art under Article 54(3) EPC 1973 either since the resulting European patent application did not validly enter the regional phase before the EPO due to non-payment of the required fees (Article 158(1) and (2) EPC 1973). Consequently, A9 is not prior art.

4.2 Document A10

A10 is a conflicting application under Article 54(3) EPC 1973, and, as a consequence, is relevant to the assessment of novelty only.

Figures 5 and 6 of A10 (see also column 5, line 44, to column 6, line 5) show incisions 7 or etched structures 8 which can be regarded as open channels. From these drawings it can only be derived that these channels are smaller in two dimensions (width and depth) than the strut. However, A10 is silent with

respect to the length of these channels, and the drawings, all being cross-sectional, do not reveal any information in this respect either. The fact that Figures 5 and 6 are comparable to Figure 2b of the patent in suit is irrelevant since the latter also includes other figures showing the length of the channels (e.g. Figure 2a) whereas no other figures are present in A10 to supplement this lack of information.

Figures 1 to 3 of A10 relate to different embodiments where the outer surface of the stent is "sculptured" to comprise micropores which may in fact be smaller in all dimensions than the strut of the stent, as argued by the appellant. But in the Board's view, this does not mean that the channels shown in Figures 5 and 6 must necessarily be shorter than the struts. Also, the micropores themselves cannot be equated to the channels as claimed.

From the fact that in the last paragraph of column 3 of A10 it is stated that only a part of the outer surface of the stent may be subjected to "sculpturing", it cannot be derived that only a part of the **length** of one of its **struts** is treated in that way. The hypothetical risks of detachment of the therapeutic agent and mechanical weakening of the stent in the event that the channels would have open ends and thus extend over the whole length of the struts (as suggested by two of the inventors of A10 in the letter dated 14 June 2006) do not imply that the disclosure of such a stent in A10 would not be enabling and that the ends of the channels must therefore necessarily be closed, their length thus being shorter than the struts. Moreover, the fact that A10 states at lines 13 to 15 of column 6 that, for

reasons of manufacturing simplicity, sculpturing is preferably performed before cutting the tube suggests that it was explicitly contemplated by the inventors of A10 to form channels having a length equal to that of the struts.

Accordingly, the feature of the channel being smaller in **all** dimensions than the strut as defined in claims 1 and 7 of the main request is not directly and unambiguously derivable from A10. This document does not therefore take away the novelty of their subject-matter under Article 54(3) EPC 1973.

4.3 Document A1

A1 is entirely devoted to providing a cover or porous layer 20 over the bioactive material 18 in order to avoid its degradation and to control its release (see especially claim 1 and "Summary of the Invention" of A1). The provision of such a porous layer is the core of the invention of A1 and essential thereto. There is no indication whatsoever in A1 that the porous layer could be omitted or considered as optional. Accordingly, A1 fails to disclose the feature of the channels having an "open top", as defined in claims 1 and 7 of the main request.

Figure 10B depicts a cross-sectional view of a strut with a square-shaped well 28' which may also be in the form of a slot or groove (column 20, lines 18 to 20), thus corresponding to a "channel". The fact that Figure 10B, which represents a cross-section of Figure 8, does not show the porous layer, contrary to the longitudinal section depicted in Figure 9, does not

imply that this layer is not present. From the overall disclosure of A1 and from the fact that claim 19 (which refers to the "apertures in the form of holes, slots, grooves or wells") depends on claim 1 (which requires the presence of a porous material positioned over the bioactive material), it is clear that the porous layer 20 must also be applied to cover the bioactive material 18 contained in the wells 28', whatever shape is given to them, as illustrated in Figures 10A to 10D.

The Board does not follow the appellant's argument that the subject-matter of claims 1 and 7 also covers intermediate products which are disclosed in A1 since the base material 14 of the stent body is first provided with bioactive material 18 before the porous layer is applied. Even though theoretically conceivable, such an interpretation appears artificial and would contradict the integral teaching of the document which is to be considered in its entirety. A1 discloses, like the patent in suit, a device ready for use and a method of its manufacturing. When the stent of A1 is finished, the porous layer is present as demonstrated above. Except for chemical products, it is not permissible to limit the disclosure of a document to an intermediate step of making the product.

The appellant further argued that, when using a very thin porous layer (in relation to the depth of the channels), the channels disclosed in A1 could still have an open top since the document does not specify that the porous layer must completely fill the channels, or must lie over their top. However, A1 is entirely silent with respect to the depth of the channels, and such an interpretation is not directly

and unambiguously derivable from the document and would not correspond to what is shown Figure 9, where the thickness of the porous layer 20 is about the same as the depth of the holes 28.

It follows that claims 1 and 7 of the main request are distinguished over the teaching of A1 (at least) in that the channels have an open top. Their subject-matter is thus new vis-à-vis this document within the meaning of Article 54(2) EPC.

5. *Inventive step*

Starting from A1 as the only relevant prior-art document for assessing inventiveness of the claimed solution, it remains to be determined whether it would have been obvious to the skilled person to leave out the porous layer disclosed in A1 and to thus arrive at channels having an open top, as suggested by the appellant.

From paragraph [0015] of the patent in suit it becomes clear that the core of the claimed invention resides in the provision of reservoirs or channels, as a new approach which is said to be advantageous over "existing technologies", i.e. in particular those mentioned in the preceding sentence involving a coating, covering or membrane. It is particularly emphasised (see the first sentence of paragraph [0017] and the second sentence of paragraph [0018]) that the reservoirs themselves, in particular their size, shape, position and number, can be used alone to control the amount and dose of drug delivered, and that the drug can thus be adequately delivered to a desired location

(see paragraph [0036] and the first sentence of paragraph [0016]). Accordingly, it is clearly derivable from the patent specification that the objective problem, which is solved by the distinguishing feature of the channels having an open top, is to achieve a localised, more direct and yet controlled administration of the therapeutic agent, with the aim of more effectively preventing restenosis.

Contrary to the appellant's assertion, the subject-matter of claims 1 and 7 of the main request cannot be regarded as a "retrospectively made invention" which was "smuggled" into the original application. The above-mentioned paragraphs of the specification were also present in the description as originally filed, and the original independent claims 1 and 8 already comprised the feature of the channels having an open top. The possibility of applying a coating or membrane over the reservoirs (mentioned in the second sentence of paragraph [0017]) is no longer pursued in the patent after amendments and therefore no longer belongs to the claimed invention. Besides, the use of a coating was acknowledged as the subject of conventional techniques (see paragraph [0015]) and is not relevant to the present invention. Therefore, the fact that certain advantages are mentioned with respect to such an optional coating is of no relevance for the assessment of inventiveness of the present solution.

The appellant's argument that the application of a porous layer such as described in A1 is expensive and that it would thus be obvious to leave it out if unneeded is based on hindsight. The whole teaching of A1 is concerned with the provision of a porous layer

for controlling the release of the therapeutic agent as an essential feature, and there is no hint or motivation whatsoever to do away with the porous layer.

It follows that the subject-matter of claims 1 and 7 of the main request is not obvious starting from A1 and considering the general knowledge of the skilled person. The Board considers that it involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël