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Datasheet for the decision of 10 February 2022

Case Number: T 0629/17 - 3.3.10

Application Number: 11185222.4

Publication Number: 2417943

IPC: A61F2/90, A61F2/06, A61L31/08, A61L31/16

Language of the proceedings: EN

Title of invention:
Drug-delivery endovascular stent for treating restenosis

Patent Proprietor:
Biosensors International Group, Ltd.

Opponent:
Abbott Cardiovascular Systems Inc.

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:

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Case Number: T 0629/17 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 10 February 2022

Appellant: (Patent Proprietor)	Biosensors International Group, Ltd. Clarendon House 2 Church Street Hamilton HM 11 (BM)
Representative:	Williams, Paul Edwin Lewis Silkin LLP 5 Chancery Lane Clifford's Inn London EC4A 1BL (GB)
Appellant: (Opponent)	Abbott Cardiovascular Systems Inc. 3200 Lakeside Drive Santa Clara, CA 95054 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 January 2017 concerning maintenance of the European Patent No. 2417943 in amended form.**

Composition of the Board:

Chair	M. Kollmannsberger
Members:	R. Pérez Carlón
	L. Basterreix

Summary of Facts and Submissions

I. Both the patent proprietor and the opponent appealed the opposition division's decision concerning the maintenance of European patent No. 1 185 222 in the form of the third auxiliary request before it.

II. Notice of opposition had been filed on grounds including lack of inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings include the following:

D4 US 6,153,252

IV. The opposition division concluded that the main request and the first and second auxiliary requests before it contained subject-matter that went beyond that of the earlier application and the application as originally filed.

The third auxiliary request, however, found the required basis. Document D4 was the closest prior art. It disclosed a coated stent of which the body was not made of metal, having a coating which contained less macrocyclic immunosuppressive triene than required by claim 1. The problem underlying the claimed invention was to provide a stent containing a greater amount of macrocyclic immunosuppressive triene. The claimed solution, characterised by the relative amount of macrocyclic triene immunosuppressive compound in the coating, would not have been obvious to the skilled person and was thus inventive.

V. With the statement setting out the grounds of appeal, the appellant-patent proprietor filed its main request and first to third auxiliary requests.

Claim 1 of the main request reads as follows:

"An endovascular stent for placement at a vascular injury site for inhibiting restenosis at the site, the stent comprising a structural member or body formed of one or more filaments and carried on the stent-body filament(s), a drug-release coating of polylactide polymers and co-polymers thereof composed of (i) 25-55 weight percent polylactic acid polymer substrate and (ii) 45-75 weight percent of a macrocyclic triene immunosuppressive compound, wherein the coating substrate is formed from poly-dl-lactide, poly-l-lactide, or poly-d-lactide, and the stent body is formed from a bioerodable polymer."

Claim 1 of auxiliary request 1 limits the stent from claim 1 of the main request by requiring the coating substrate to be formed from poly-dl-lactide.

Claim 1 of the second auxiliary request limits the stent from claim 1 of the main request by requiring the drug-release coating to be "carried" (the board understands that "coated" was meant) on all sides of the stent-body filaments.

Lastly, claim 1 of the third auxiliary request requires all the features of claim 1 of the first and second auxiliary requests. It thus requires the coating substrate to be formed from poly-dl-lactide and the coating to be on all sides of the stent-body filament(s).

Claim 1 of the third auxiliary request corresponds to claim 1 of the request found allowable by the opposition division.

VI. The appellant-patent proprietor's arguments on the issue of inventive step were as follows.

The appellant-patent proprietor agreed with the opposition division's reasoning and conclusion. The stent from claim 1 of the third auxiliary request was inventive in view of document D4. The skilled person would have expected the stents from D4 to contain the highest technically possible amount of the drug, since thin drug layers were preferred. If the drug were rapamycin, 33 weight percent was as much as it could be coated. For that reason, the skilled person would have considered that increasing the relative amount of macrocyclic triene immunosuppressive compound lacked a reasonable expectation of success.

VII. The appellant-opponent agreed with the opposition division that document D4 was a suitable starting point for examining inventive step. It considered the relative amount of macrocyclic triene immunosuppressive compound in the coating and the material of the stent body to be distinguishing features. It also agreed with the formulation of the problem in the decision under appeal. It argued, however, that the claimed solution would have been obvious to the skilled person.

VIII. The board issued a communication dated 22 September 2020. The board was of the view that the stent from claim 1 of all the requests on file was not inventive in view of D4.

IX. The appellant-patent proprietor did not file any substantive reply to the board's communication. It merely informed the board that it would not be represented at the already scheduled oral proceedings, which were subsequently cancelled.

X. The parties' final requests were as follows:

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

- The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained with the claims of the main request or of auxiliary requests 1 and 2, all requests as filed with the statement of grounds of appeal, or that the appellant-opponent's appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Auxiliary request 3 - inventive step

2.1 The appellant-patent proprietor requested, as its third auxiliary request, that the appellant-opponent's appeal be dismissed (statement of grounds of appeal, third paragraph). It filed a third auxiliary request, which was nevertheless not identical to the request found allowable by the opposition division. The differences are minor. Claim 1 does not differ.

2.2 Claim 1 of the third auxiliary request relates to an endovascular stent having

a body formed from a bioerodable polymer and having one or more filaments which carried

a drug-release coating composed of

(i) 25-55 weight percent polylactic acid polymer substrate formed from poly-dl-lactide and
(ii) 45-75 weight percent of a macrocyclic triene immunosuppressive compound.

2.3 Closest prior art

The opposition division concluded that Example 7 of document D4 was the closest prior art. Both appellants considered D4 a suitable starting point for examining inventive step, and the board sees no reason to differ.

Example 7 of D4 discloses a number of stents coated with rapamycin, which is a macrocyclic triene immunosuppressive compound.

The stent disclosed in column 12, lines 55-63, of D4 is represented in Figure 7 by a full circle. The stent body is Cording P-S 153 (column 10, line 9), which is made of metal. This stent was coated following the process in Example 1 of D4, by applying a solution having 33.3 weight percent rapamycin to it, the remainder being an epsilon-caprolactone-co-lactide copolymer.

2.4 It was undisputed that the stent from claim 1 differed from that in Example 7 of D4 by virtue of

- the relative amount of polymer substrate and macrocyclic immunosuppressive triene in the coating and

- the type of material of the stent body.

2.5 Technical problem underlying the invention

The opposition division defined the technical problem underlying the claimed invention as that of providing a stent having a greater total amount of immunosuppressive macrocyclic triene.

Neither of the appellants disagreed with the formulation of the technical problem by the opposition division.

2.6 Solution

The solution to this technical problem is the coated stent containing an immunosuppressive macrocyclic triene from claim 1, characterised in that the coating contains 45-75 weight percent of macrocyclic immunosuppressive triene.

It was undisputed that the material of the stent body did not contribute to solving the problem of increasing the total amount of immunosuppressive macrocyclic triene. It was also not disputed that D4 disclosed bioabsorbable aliphatic polyesters as being suitable for the stent body (column 3, line 18).

2.7 Success

It was also undisputed that the problem of providing a stent with a greater amount of immunosuppressive macrocyclic triene had been credibly solved by the stent from claim 1, as a consequence of increasing its concentration in the coating.

2.8 It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious to the skilled person in view of the prior art.

2.8.1 D4 discloses that high-concentration coatings are the preferred means for achieving high drug loading (column 1, lines 52-54). D4 thus hints at the claimed solution.

The appellant-patent proprietor does not dispute that thinner coatings were known to be advantageous (letter dated 5 October 2017, page 3, last paragraph, with reference to Dr Dutta's declaration). D4 corroborates that thicker coatings are not desired (column 1, line 54-58). It refers in particular to the problem of dispersion through thicker coatings, which affects sustained release.

An obvious way to increase the drug loading of a coated stent which does not have the known drawbacks of a thicker coating is to increase the concentration of the drug in said coating.

Enhancing the relative amount of immunosuppressive macrocyclic triene compared with that disclosed in Example 7 of D4 would thus have been obvious to the skilled person seeking to increase the total amount of said drug in a stent. By doing so, they would have

arrived at the claimed solution without exercising inventive skill.

The claimed solution is thus not inventive (Article 56 EPC).

2.8.2 The appellant-patent proprietor argued that enhancing the relative amount of immunosuppressive macrocyclic triene in the coating was expected to negatively affect its mechanical properties. It could even lead to the failure of the stent. For this reason, the skilled person would not have had any expectation of success. This was also the view of the opposition division.

However, the skilled person seeking a stent having a greater total amount of immunosuppressive triene would have tried to increase its loading on the stent, even if some difficulties could have arisen.

Even if a stent with a higher drug concentration in the coating does not have optimum mechanical properties, claim 1 does not require any mechanical property over and above being suitable for being placed at an injury site. No specific mechanical property is part of the technical problem underlying the claimed invention, either.

This argument is thus not convincing.

2.8.3 The appellant-patent proprietor also argued that the drug concentration in the coating disclosed in D4 (33 weight percent) was to be considered to be the maximum technically possible concentration for rapamycin.

However, document D4 hints at higher drug

concentrations in column 9, lines 20-24. There is thus no reason to consider 33 weight percent to be the highest technically possible concentration. The relative amount of the drug could also have been chosen for reasons of pharmacological dosage or release speed. D4 does not provide any information whatsoever in this respect.

This argument is not convincing either.

3. Main request, first and second auxiliary requests

The stent from claim 1 of the third auxiliary request is an embodiment of the stent from claim 1 of every request on file. In fact, it is undisputed that the distinguishing features of the stent from claim 1 over D4 are the same, regardless of the request under consideration.

The stent from claim 1 of the main request and of the first and second auxiliary requests is thus not inventive for the same reasons as those given for the third auxiliary request.

4. Conclusion

None of the appellant-patent proprietor's requests is allowable. According to Article 101(3)(b) EPC the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

C. Rodríguez Rodríguez M. Kollmannsberger

Decision electronically authenticated