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Datasheet for the decision of 10 February 2022

Case Number: T 1628/17 - 3.3.10

Application Number: 10185483.4

Publication Number: 2316377

IPC: A61F2/02

Language of the proceedings: EN

Title of invention:
Drug-Delivery Endovascular Stent

Patent Proprietor:
Biosensors International Group, Ltd.

Opponent:
Boston Scientific Scimed, Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - added subject-matter (yes)

Decisions cited:
G 0009/92, G 0004/93

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1628/17 - 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:	Ablett, Graham Keith Lewis Silkin LLP 5 Chancery Lane Clifford's Inn London EC4A 1BL (GB)
Respondent: (Opponent)	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 May 2017 concerning maintenance of the European Patent No. 2316377 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor appealed the decision of the opposition division concerning maintenance of European patent No. 2316377 in amended form, on the basis of the fourth auxiliary request then pending.

II. The opposition was filed on the grounds set out in Article 100(a) and (c) EPC.

III. The opposition division concluded that claim 1 of each of the main request and the first to third auxiliary requests applicable at that time contained subject-matter extending beyond that of the earlier application.

The opposition division also concluded that the fourth auxiliary request then pending, which is the appellant's fifth auxiliary request in these appeal proceedings, was allowable. As the patent proprietor is the sole appellant, this part of the decision is not to be examined in these appeal proceedings (G 9/92, G 4/93, headword I).

IV. With the statement setting out the grounds of appeal, the appellant filed a main request and first to fifth auxiliary requests. The fifth auxiliary request corresponds to the request found allowable by the opposition division.

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, comprising a tubular body which is radially expandable

from a contracted state to an expanded state, wherein the diameter of the stent in its expanded state is at least twice that of the stent in its contracted state, the tubular body formed of a lattice of connected filaments, each filament having top and side regions and an inside surface, and a drug-release coating layer formed from a polylactic acid polymer substrate selected from the group consisting of poly-dl-lactic acid, poly-d-lactic acid, and poly-l-lactic acid, and copolymers thereof containing a macrocyclic triene immunosuppressive restenosis-inhibiting drug, said layer applied as a fluid composition that coats the top and side regions, but not the inside surfaces, of said filaments."

Claim 1 of the first auxiliary request, in addition to the feature of claim 1 of the main request, specifies that the drug-release coating layer is formed from a poly-dl-lactide.

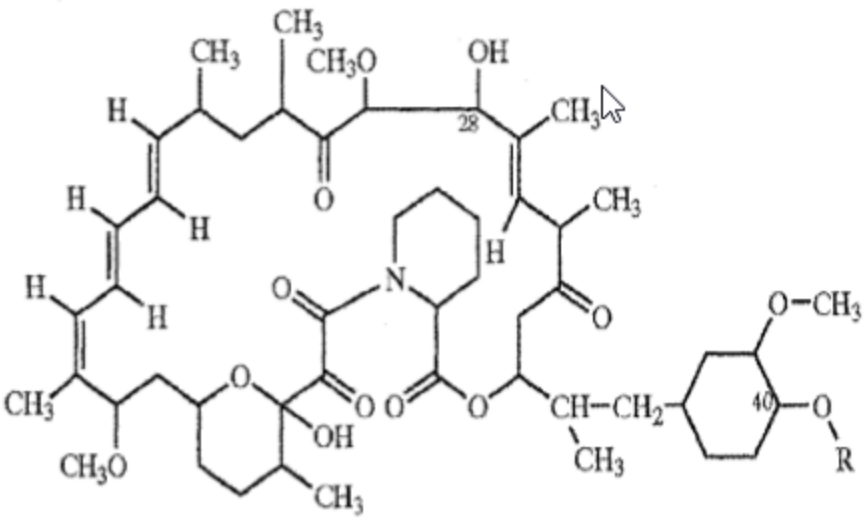
Claim 1 of the second auxiliary request further specifies that the tubular body of the stent is a tubular metal body.

Claim 1 of the third auxiliary request specifies that said tubular metal body is formed from expandable tubular members linked by filaments.

Claim 1 of the fourth auxiliary request has the features of claim 1 of the first auxiliary request and additionally specifies the following:

"wherein the drug release coating has a thickness of between 3-25 microns, and is composed of (i) 20 and 70 weight percent of the poly-dl-lactide polymer substrate and (ii) 30-80 weight percent of the macrocyclic triene

immunosuppressive drug, wherein the drug has the form:



where (i) R is H or CH_2-X-OH, and X is a linear or branched alkyl group containing 1 to 7 carbon atoms."

V. The arguments of the appellant relevant to the present decision were as follows.

The feature "wherein the diameter of the stent in its expanded state is at least twice that of the stent in its contracted state" found a basis on page 9, lines 5 to 7, of the earlier application. Although lines 9 and 10 of that page specified a "general stent-body architecture of linked, expandable tubular members", claim 1 specified an equivalent feature, namely "a tubular body formed of a lattice of connected filaments".

The feature "macrocyclic triene immunosuppressive restenosis-inhibiting drug" found a basis on page 4, lines 5-6; page 12, lines 7 to 9, and page 14, lines 24 to 26, of the earlier application.

Thus, the earlier application provided the required basis for claim 1 of the main request and of auxiliary

requests 1 to 3.

Claim 1 of the fourth auxiliary request found a basis on page 4, lines 8 to 18, and page 11, lines 16 to 23 of the earlier application.

VI. The respondent (opponent) argued that the features "wherein the diameter of the stent in its expanded state is at least twice that of the stent in its contracted state" and "macrocyclic triene immunosuppressive restenosis-inhibiting drug" were disclosed in the earlier application in combination with further limitations, which were not features of claim 1. The same was argued with respect to the general formula of claim 1 of auxiliary request 4. For these reasons, claim 1 of the main request and of auxiliary requests 1 to 4 contained subject-matter not disclosed in the earlier application.

VII. In a communication dated 22 September 2020, the board informed the parties that it was inclined to conclude that the main request and the first to fourth auxiliary requests contained subject-matter not disclosed in the earlier application.

VIII. The appellant informed the board that it would not be attending the oral proceedings to which it had already been summoned.

IX. The board cancelled the oral proceedings.

X. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the first to fifth

auxiliary requests, all of which requests had been filed with the statement of grounds of appeal, the fifth auxiliary request corresponding to the request found allowable by the opposition division.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments - main request

The patent arises from a divisional application of the European application published as European patent No. 1505930, originating from international application WO 03/090818. References to the earlier application in this decision relate to the latter.

2.1 Feature *"wherein the diameter of the stent in its expanded state is at least twice that of the stent in its contracted state"*

2.1.1 The opposition division concluded that this feature did not find the required basis in the earlier application in the context of claim 1 of the main request. The feature was to be found word for word on page 9, lines 5 to 7. However, it was disclosed in the context of stents of specific characteristics, which were not features of claim 1.

The board agrees with the reasoning and conclusion of the opposition division on this point.

2.1.2 The appellant argued that the passage on page 9, lines 9 to 10, disclosed stents having a "general stent-body

architecture of linked, expandable tubular members". Claim 1 specified "a tubular body formed of a lattice of connected filaments", which was equivalent to that wording.

However, the passage of the earlier application containing the feature "wherein the diameter of the stent in its expanded state is at least twice that of the stent in its contracted state" word for word starts on page 8, line 25 and extends to page 9, line 9.

This embodiment relates to stents having specific construction details, which are not features of claim 1. The stent has "a plurality of linked tubular members by filaments". Furthermore, these members are specified as having a zig-zag, sawtooth or sinusoidal wave structure. In addition, the members are linked by axial links joining the peaks and troughs of adjacent members. This type of construction allows expansion of the stent with little or no change in its length. Last, the stent of the earlier application has a defined diameter in its contracted state, and a defined length. None of these features are included in claim 1 of the main request.

The board is thus not convinced by the appellant's argument.

2.2 Feature *"macrocyclic triene immunosuppressive restenosis-inhibiting drug"*

There is no basis in the earlier application for this feature in the context of claim 1 of the main request: not on page 4, lines 5 to 6, not on page 12, lines 7 to 9, and not on page 14, lines 24 to 26.

2.2.1 The passage on page 12 discloses a coating having the specified "macrocyclic triene immunosuppressant compound" in combination with poly-dl-lactide polymer substrate, defined proportions of the two components, a specific coating thickness, a specific underlayer in terms of composition and thickness and a total amount of drug with respect to the stent. None of these features is specified by claim 1 of the main request.

2.2.2 The passage on page 14 discloses an "anti-restenosis drug, such as a macrocyclic triene immunosuppressant compound" in combination with poly-dl-lactide and defined proportions of the two. These limitations are not specified by claim 1 either.

2.2.3 Last, the passage on page 4 relates to the stent disclosed in the preceding passage, which starts on page 3. This stent has a number of features not specified by claim 1 of the main request. These include the proportions of components of the coating, the use of poly-dl-lactide and an undercoat of defined thickness.

In addition, the passage on page 4, lines 5-6 continues by defining the composition of the undercoat (parylene polymer), its thickness, the thickness of the coating and the proportion of the drug. None of these features are specified by claim 1 of the main request either.

The main request is thus not allowable.

3. Amendments - first to third auxiliary requests

The objections in points 2.1 and 2.2 above apply in the same manner to claim 1 of each of the first to third auxiliary requests. These requests are not allowable

either.

4. Amendments - fourth auxiliary request

Claim 1 of the fourth auxiliary request does not find a basis in the earlier application.

On page 4, lines 8 to 18, the earlier application discloses the immunosuppressive drug specified by claim 1. However, it is disclosed in the context of a stent with proportions of drug and polymer which do not correspond to those of claim 1.

On page 11, lines 16 to 23, the earlier application discloses the immunosuppressive drug specified by claim 1. However, this is in the context of a stent with different proportions of polymer and drug from those specified in claim 1 of the fourth auxiliary request. In addition, it specifies a bioerodable poly-dl-lactide polymer (page 11, line 1) such as poly-dl-lactic acid. However, claim 1 does not specify that the poly-dl-lactide is bioerodable.

For these reasons, the fourth auxiliary request is not allowable either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

C. Rodríguez Rodríguez M. Kollmannsberger

Decision electronically authenticated