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Datasheet for the decision of 15 December 2015

Case Number: T 1856/12 - 3.3.07

Application Number: 02797211.6

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Title of invention:
SELECTIVE ADSORPTION DEVICES AND SYSTEMS

Applicant:
Renaltech International LLC

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter (yes) - all requests

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Case Number: T 1856/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 15 December 2015

Appellant: (Applicant)	Renaltech International LLC 320 East 65th Street, Suite 116 New York, NY 10021 (US)
Representative:	Potter Clarkson LLP The Belgrave Centre Talbot Street Nottingham, NG1 5GG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 April 2012 refusing European patent application No. 02797211.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	D. Semino
	P. Schmitz

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division announced at the oral proceedings on 15 March 2012 refusing European patent application n° 02 797 211.6.

The application as originally filed included three independent device claims, namely claim 1 directed to an intravenous catheter and claims 17 and 33 directed to blood treatment assemblies comprising a first unit, a second unit and coupling means.

II. The decision was based on 3 sets of claims filed respectively during oral proceedings on 15 March 2012 (main request), with letter of 2 March 2012 (auxiliary request 1) and with letter of 18 January 2012 (auxiliary request 2). Claim 1 of the main request read as follows:

"1. A device (18, 30) for treating blood or other physiologic fluid comprising:
a housing (32); and
an adsorption medium (34) contained in the housing;
an inlet (33) for conveying the blood or physiologic fluid into the housing for contact with the adsorption medium; and
an outlet (36) for conveying the blood or physiologic fluid from the housing after contact with the adsorption medium,
characterized in that the adsorption medium comprises a group of porous polymeric particles (76) having a porous hydrophobic core (78) formed from a crosslinked divinylbenzene material and a biocompatible, hydrophilic coating (80) comprising a polyvinylpyrrolidone material."

Claim 1 according to auxiliary request 1 read as follows:

"1. A blood treatment assembly (20) comprising:
a first unit (24, 28) comprising an element for processing blood drawn from an individual;
a second unit (18, 30) comprising an adsorption medium (34) that removes a targeted compound from the blood by selective adsorption, wherein the adsorption medium comprises a group of porous polymeric particles (76) having a porous hydrophobic core (78) formed from a divinylbenzene copolymer and a biocompatible, hydrophilic coating (80) comprising a polyvinylpyrrolidone polymer; and
coupling means for integrally coupling the first and second units together to form the blood treatment assembly that is supplied to a user as a single, integrated unit."

Claim 1 of auxiliary request 2 corresponded to claim of the main request wherein the adsorption medium was defined as comprising "a group of porous polymeric particles (76) having a porous hydrophobic core (78) formed from a divinylbenzene copolymer and a biocompatible, hydrophilic coating (80) comprising a polyvinylpyrrolidone polymer".

III. The decision under appeal can be summarised as follows:

a) The main request fulfilled the requirements of Article 123(2) EPC in view of the embodiment on page 59 of the application as filed. However, the subject-matter of claims 1 to 8 of the main request was not new over the disclosure of document D3 (WO-A-00/62836), filed by the same

applicant as the application under analysis. The difference stated by the applicant, namely that the divinylbenzene polymer in D3 was not crosslinked, could not be accepted in view of the fact that divinylbenzene itself was a crosslinker.

b) Claim 1 of auxiliary request 1 did not meet the requirements of Article 123(2) EPC because the combination of a porous, hydrophobic core formed from a divinylbenzene copolymer and a biocompatible, hydrophilic coating comprising a polyvinylpyrrolidone polymer was not disclosed in the original application. Moreover, the novelty objection raised for the main request also applied for auxiliary request 1.

c) Claim 1 of auxiliary request 2 did not meet the requirements of Article 123(2) EPC for the same reasons as the ones valid for claim 1 of auxiliary request 1.

IV. The applicant (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted six sets of claims as main request and as first to fifth auxiliary requests respectively.

Claim 1 of the main request corresponded to claim 1 of the main request on which the decision was based with the amendment of the definition of the device as follows (deletions in strike-through, additions in bold): "for ~~treating~~ **removing cytokines from** blood or other physiologic fluid **to reduce the population of cytokines**".

Claim 1 of the third auxiliary request read as follows:

"1. Use of an adsorption medium (34) comprising a group of porous polymeric particles (76) having a porous hydrophobic core (78) formed from a cross-linked divinylbenzene material and a biocompatible, hydrophilic coating (80) comprising a polyvinylpyrrolidone material in a device (18, 30) for removing cytokines from blood or other physiologic fluid to reduce the population of cytokines."

Claim 1 of the first and fourth auxiliary requests corresponded to claim 1 of the main request and of the third auxiliary request respectively wherein the purpose "to reduce the population of cytokines" was amended to "without producing an offsetting result of generating additional cytokines". Claim 1 of the second and fifth auxiliary requests corresponded to claim 1 of the first and fourth auxiliary requests respectively with the specification that the adsorption medium has "a biocompatibility index of not greater than 14 determined in accordance with the method disclosed in the description".

V. In a communication sent in preparation of oral proceedings, the Board emphasised *inter alia* (point 1.1 in the communication) that it had difficulties in acknowledging the claims and passages of the original application indicated by the appellant and the example cited in the decision as a sufficient basis for claim 1 of the main request. The same issue *inter alia* applied to claim 1 according to the auxiliary requests (point 3 in the communication). In the communication objections of lack of novelty, lack of sufficiency and lack of inventive step were also raised in great detail for the

requests on file (points 2, 3 and 4 of the communication).

VI. Oral proceedings were held on 15 December 2015 in the absence of the appellant as announced with a letter of 7 December 2015, in which the appellant had also withdrawn his request for oral proceedings.

VII. In the statement setting out the grounds of appeal the appellant indicated the basis in the application as originally filed for the claims of all requests in four tables attached to the statement and added some further passages of the original application with regard to some specific amendments when illustrating the requests (pages 3 and 4 of the statement). As far as claim 1 of the main request was concerned, original claims 1, 7, 8 and 11 as well as passages on pages 10, 32, 39 and 40 were cited in the first table attached to the statement. Additional passages were given in relation to the specific feature "removing cytokines... to reduce the population of cytokines". With regard to claim 1 of the first and second auxiliary requests additional passages were indicated only with regard to the differences with respect to claim 1 of the main request. For claim 1 of the third to fifth auxiliary requests the same claims and passages were cited as for claim 1 of the main request and of the first and second auxiliary requests respectively.

No other arguments with regard to the requirements of Article 123(2) EPC were submitted by the appellant, neither before, nor after the communication of the Board.

VIII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of

one of the six sets of claims filed as main request and first to fifth auxiliary requests with the statement setting out the grounds of appeal.

Reasons for the Decision

Amendments - main request

1. Claim 1 of the main request concerns a device for removing cytokines from blood or other physiologic fluid comprising a housing, an adsorption medium in the housing, an inlet and an outlet, wherein the adsorption medium comprises a group of porous polymeric particles having a porous hydrophobic core formed from a crosslinked divinylbenzene material and a biocompatible, hydrophilic coating comprising a polyvinylpyrrolidone material.

1.1 The claims cited by the appellant, namely original claim 1 as well as claims 7, 8 and 11 dependent thereon, concern an intravenous catheter comprising an in-line housing containing a material which removes a targeted compound from blood, wherein the material can comprise polymeric particles which may be prepared, among others, by the polymerisation of divinylbenzene and may be surface modified, among others, by N-vinylpyrrolidine. Those claims disclose a much more specific device (a catheter) than the one of claim 1 of the main request with an adsorption medium which does not correspond to the very specific one of claim 1 of the main request (divinylbenzene is crosslinked and the coating is a polyvinylpyrrolidone material). Therefore, they do not provide a basis for the claimed device, nor even, possibly in combination with other parts of the disclosure, a reasonable starting point for it. Also the other independent claims (claims 17 and 33), which

concern blood treatment assemblies comprising a first unit, a second unit and coupling means, cannot provide a basis for claim 1 of the main request.

1.2 The same holds for the passages of the description cited by the appellant.

1.2.1 The passage on page 10 (lines 21 to 23) mentions an adsorption material which comprises polymeric particles with a coating to impart biocompatibility. It is, however, in the context of a catheter or of a blood treatment assembly with coupled first and second units (page 10, lines 3 to 20) and therefore suffers from the same limits as the claims (the device is more specific than the one of claim 1 of the main request and the specific medium is not disclosed).

1.2.2 The passage on page 32 (lines 4 to 19) discloses a unitary extracorporeal device with an inlet, an outlet and a housing containing a medium. An adsorption medium is disclosed starting on page 39 (page 39, line 1 to page 40, line 3), including polymeric particles with a hydrophobic core which can be composed of crosslinked polymeric material prepared from, among several other polymers, divinylbenzene and a biocompatible hydrophobic coating of, among others, polyvinylpyrrolidone. Here again the device is more specific than the one of claim 1 of the main request (it is an extracorporeal device) and the adsorption medium is not the specific one (which may result only from a selection out of two lists), so that also these passages do not provide an appropriate basis for claim 1 of the main request.

1.3 In the decision under appeal a specific example (example 1 starting on page 59 of the application as

originally filed) was cited as a basis for claim 1 of the (then) main request. Indeed example 1 discloses the specific medium of claim 1 of the main request (page 59, lines 19 to 23), however in the context of an extracorporeal device (by reference to figure 3 described on page 32) for the removal of specific cytokines (TNF, IL-6, IL-10) from blood. A basis for the specific medium in the broad context of a generic device (not necessarily extracorporeal) for removal of (any) cytokines from (any) physiological fluid is not given by the specific example.

1.4 For these reasons the device of claim 1 of the main request is not directly and unambiguously derivable from the application as originally filed and the requirements of Article 123(2) EPC are not met.

Amendments - first and second auxiliary requests

2. Claim 1 of the first and second auxiliary requests corresponds to claim 1 of the main request with the reformulation of the purpose ("without producing an offsetting result of generating additional cytokines" instead of "to reduce the population of cytokines", both requests) and an additional condition on the biocompatibility index of the adsorption medium (second auxiliary request).

2.1 The amendments are not meant to address the issue under Article 123(2) EPC raised for the main request, which indeed remains equally valid for claim 1 of the first and second auxiliary requests.

2.2 The devices of claim 1 of the first and second auxiliary requests do not meet therefore the

requirements of Article 123(2) EPC for the same reasons as given for the main request (point 1, above).

Amendments - third to fifth auxiliary requests

3. Claim 1 of the third auxiliary request is a use claim directed to the use of an adsorption medium comprising a group of porous polymeric particles having a porous hydrophobic core formed from a cross-linked divinylbenzene material and a biocompatible, hydrophilic coating comprising a polyvinylpyrrolidone material in a device for removing cytokines from blood or other physiologic fluid to reduce the population of cytokines.

3.1 It concerns therefore the use of the adsorption medium of the characterising part of claim 1 of the main request in a device solely defined by its purpose ("removing cytokines from blood or other physiologic fluid to reduce the population of cytokines") and therefore even broader than the one of claim 1 of the main request (the latter including, in addition to the adsorption medium, a housing containing it, an inlet and an outlet).

3.2 The objection under Article 123(2) EPC raised for claim 1 of the main request still applies therefore for even stronger reasons to claim 1 of the third auxiliary request. In this respect it is relevant that the same original claims and the same passages of the original description were cited by the appellant for claim 1 of the third auxiliary request as for claim 1 of the main request.

4. Claim 1 of the fourth and fifth auxiliary requests corresponds to claim 1 of the third auxiliary request

with the same amendments as introduced in the first and second auxiliary requests with respect to the main request.

4.1 Here again, the amendments do not address the issue under Article 123(2) EPC and the same objection applies.

4.2 The devices of claim 1 of the third to fifth auxiliary requests do not meet therefore the requirements of Article 123(2) EPC for the same reasons as given for the main request (point 1, above).

Conclusions

5. As all the requests on file do not meet the requirements of Article 123(2) EPC, the appeal is to be dismissed already for this reason. It is not necessary therefore for the Board to conclude on the issues of novelty, sufficiency of disclosure and inventive step, which were objected to in the communication sent in preparation of the oral proceedings (point V, above).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated