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**Datasheet for the decision
of 19 June 2009**

Case Number: T 0791/08 - 3.3.02

Application Number: 96906490.6

Publication Number: 0809515

IPC: A61K 47/48

Language of the proceedings: EN

Title of invention:

Therapeutic inhibitor of vascular smooth muscle cells

Patentee:

Boston Scientific Limited

Opponent:

Terumo Kabushiki Kaisha
CONOR MEDSYSTEMS
Medinol Ltd.

Headword:

Inhibitor/BOSTON SCIENTIFIC LIMITED

Relevant legal provisions:

EPC Art. 113(1)
EPC R. 67

Relevant legal provisions (EPC 1973):

-

Keyword:

"Remittal - yes: procedural violation"

Decisions cited:

-

Catchword:

-



Case Number: T 0791/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 19 June 2009

Applicant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 29 February 2008
revoking European patent No. 0809515 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

- I. European patent No. 809 515, based on European application No. 96 906 490.6, was granted on the basis of 15 claims.

Independent claim 1 as granted read as follows:

"1. An intravascular stent comprising a matrix and a coating on said matrix, in which the coating and the matrix together comprise an amount of a cytoskeletal inhibitor and/or a cytostatic amount of an inhibitor of smooth muscle cell proliferation effective to inhibit stenosis or reduce restenosis following placement of the stent in a vessel."

- II. Notices of opposition were filed against the patent by opponents 1 to 3 under Article 100(a), (b) and (c) EPC on grounds related to Articles 53(c), 54, 56, 83 and 123(2) EPC.
- III. By decision pronounced on 30 January 2008, the opposition division revoked the patent under Article 101(3)(b) EPC.

The main request filed with letter dated 18 January 2008 was rejected because its subject-matter contravened the requirements of Article 123(2) EPC. In the opposition division's view, the feature "cytostatic amount" in claim 1 was not disclosed in the application as originally filed and "not all possible combinations of cytoskeletal inhibitor and smooth muscle cell proliferation inhibitor in the matrix and in the coating, which are encompassed by claim 1, are directly

and unambiguously disclosed in the originally filed application".

Auxiliary request 1 filed during the oral proceedings was rejected under Article 123(2) EPC for the same reasons as the main request. The opposition division moreover considered that the deletion of the feature "cytostatic" extended the scope of protection, which infringed the requirements of Article 123(3) EPC.

Auxiliary requests 2 to 5 filed during the oral proceedings were not admitted into the proceedings because they did not *prima facie* meet, among other, the requirements of Article 123(2) EPC.

- IV. The appellant (patentee) lodged an appeal against the above decision.

- V. In its grounds of appeal dated 11 June 2008, the appellant submitted that it had not been given a fair opportunity to present and defend its case, such that its right to be heard had been severely compromised.

In that respect, it held that the opposition division had put it in a position to have only one opportunity to file a further request in order to deal with a newly raised objection, namely the one relating to "cytostatic amount", and with a new unsubstantiated view of the opposition division concerning unsupported combinations.

It submitted that admitting only one request into the proceedings in the presence of a new objection raised for the first time at the hearing, and denying an

explanation both during the hearing and in the contested decision in support of the decision to consider that not all possible combinations of the main request of 18 January 2008 were supported by the original application constituted a substantial procedural violation on the part of the opposition division.

It also submitted that there was a further procedural violation in that the opposition division had wrongly decided not to admit auxiliary request 5 into the proceedings.

With its grounds of appeal, it filed a new main request and auxiliary requests 1 to 21 and provided arguments as to why these requests fulfilled the requirements of Article 123(2) and (3) EPC.

Claim 1 of the set of claims 1 to 4 of the main request reads:

1. An intravascular biodegradable stent comprising a matrix and a coating on said matrix, in which the coating and the matrix together comprise an amount of a cytoskeletal inhibitor or a cytostatic amount of an inhibitor of smooth muscle cell proliferation, effective to inhibit stenosis or reduce restenosis following placement of the stent in a vessel, wherein the coating is a biodegradable coating or porous or permeable non biodegradable coating comprising a sustained release dosage form of the inhibitor, and the matrix has the inhibitor impregnated therein to provide a faster release of the therapeutic agent from the coating followed by delayed release of the therapeutic

agent that is impregnated in the stent matrix upon degradation of the stent matrix.

VI. In their reply to the grounds of appeal, respondents R1 to R3, respectively opponents 01 to 03, contested that the opposition division had committed a procedural violation.

They submitted that Article 123(2) was a ground of opposition raised by opponent 01 in its notice of opposition and that the opposition division had in any case the right to examine the facts of its own motion under Article 114(1) EPC, even for the first time during the oral proceedings.

They also argued that the opposition division was under no duty to provide the proprietor with any information on the patent claims, so it had no duty to identify the combinations of the two inhibitors claimed but not originally disclosed.

They also held that the objections were both discussed at length during the oral proceedings.

They moreover submitted that the patent should be revoked under Articles 123(2) and (3), 84, 83, 54 and 56 EPC.

VII. In a communication dated 16 February 2009 and in a further communication dated 29 May 2009, the board expressed its agreement with the appellant's written submissions that the right to be heard had been violated by the opposition division (Article 113(1))

EPC), so the case should be directly remitted to the opposition division.

VIII. Oral proceedings were held on 19 June 2009.

During these proceedings, the parties mainly repeated their written submissions.

IX. The appellant (patentee) requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution based on the main request filed with letter dated 11 June 2008. It also requested reimbursement of the appeal fee.

The respondents (opponents 01 to 03) requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2.1 Article 113 (1)EPC

The appellant provided in its grounds of appeal various arguments as to why it had not been given a fair opportunity to present and defend its case, such that its right to be heard had been severely compromised (see above, under V).

In that respect, the board observes that none of the parties has contended that the feature "cytostatic amount", which was already present in claim 1 as

granted, was contested for the first time under Article 123(2) EPC during the oral proceedings, so that the appellant could not expect this objection. This is confirmed by the minutes, from which it appears that the objection was raised by opponent 02 and dealt with between 9:48 and 10:50 am (page 2, paragraph 2).

The board also notes that the decision does not indicate which combinations falling under the scope of claim 1 are not disclosed in the application as originally filed.

The minutes again confirm that during the oral proceedings, despite the appellant's attempts to clarify the opposition division's objection, no indication was provided (page 2, paragraphs 2 and 4).

It also appears from the minutes that, as held by the appellant, the opposition division restricted the appellant's reaction faced with the above situation to a single opportunity (page 2, paragraph 4).

Finally, as contended by the appellant during the oral proceedings, it would indeed appear from the minutes that it was not given the opportunity to present its case in relation to auxiliary requests 2 to 5 (page 3, last paragraph, and sheet 2/1 of form 2309.2).

In fact, during the oral proceedings the appellant drew the board's attention to the minutes on page 3, last paragraph, indicating that the proceedings concerning auxiliary requests 2 to 5 were started at 14:35 and to sheet 2/1 of form 2309.2 indicating that the oral proceedings were closed at 14:38, namely 3 minutes later.

This was also not contested by the parties during the oral proceedings.

Under these circumstances, the board is very much inclined to believe the appellant's assertion that it was not given a fair opportunity to present and defend its case, such that its right to be heard was severely compromised.

In particular, under the very particular circumstances of this case the board considers that the appellant should have been given more than a single opportunity to overcome the objections.

Accordingly, the board considers that the right to be heard has been violated, which constitutes a second severe procedural violation. There is therefore no need to consider further alleged procedural violations.

- 2.2 The board agrees with the parties that Article 123(2) was a ground of opposition raised by opponent 01 in its notice of opposition and that the opposition division had in any case the right to examine the facts of its own motion under Article 114(1) EPC, even for the first time during the oral proceedings.

This does however not put into question the necessity of having a fair procedure.

The board also agrees that the opposition division is under no duty to provide the proprietor with any information on the patent claims. The objection raised must however be clearly understandable, which was

apparently not the case at least for the appellant. In that respect, the board observes that no specific combinations have been specifically identified so far in the file.

As to the statement that the objections were both discussed at length during the oral proceedings, the board has some doubt in the light of the fact that the minutes rather confirm the appellant's submission that it was given three minutes to present its case in relation to auxiliary requests 2 to 5.

3. Under these circumstances, the decision under appeal must be set aside, and in accordance with the established case law of the boards of appeal the case must be remitted to the department of first instance for further prosecution.

The appeal is allowed to the extent that the decision under appeal is set aside, and the appeal fee is reimbursed pursuant to Rule 67 EPC, on account of the substantial procedural violation constituted by non-compliance with Article 113(1) EPC.

The board considers that it is also not appropriate to decide on the issues relating to the objections under Article 123(2), contrary to the respondents' view, since this would deprive the appellant of the possibility of having two **fair** instances, which was precisely the object of the appellant's appeal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of the main request filed with letter dated 11 June 2008.
3. The appeal fee is reimbursed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald