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Datasheet for the decision of 19 December 2019

Case Number: T 0949/13 - 3.3.01

Application Number: 94907364.7

Publication Number: 0681475

IPC: A61K31/535

Language of the proceedings: EN

Title of invention:
THERAPEUTIC INHIBITORS OF VASCULAR SMOOTH MUSCLE CELLS

Patent Proprietor:
Boston Scientific Limited

Opponent:
Medrad, Inc.

Headword:
Taxol to avoid restenosis/BOSTON SCIENTIFIC

Relevant legal provisions:
EPC Art. 84
EPC R. 115(2)
RPBA Art. 15(3)

Keyword:
Claims - clarity - main and auxiliary requests (no)
Summons to oral proceedings - continuation of proceedings without duly summoned parties

Decisions cited:
T 0560/09

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 0949/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 19 December 2019

Appellant: (Opponent)	Medrad, Inc. One Medrad Drive Indianola, PA 15051 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Respondent: (Patent Proprietor)	Boston Scientific Limited Clarendon House 2 Church Street Hamilton HM11 (BM)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 March 2013 concerning maintenance of the European Patent No. 0681475 in amended form.**

Composition of the Board:

Chairman	A. Lindner
Members:	G. Seufert
	P. de Heij

Summary of Facts and Submissions

I. The opponent (appellant) lodged an appeal against the opposition division's interlocutory decision on the amended form in which European patent No. 0 681 475 could be maintained.

II. The present decision refers to the following documents:

D2 WO 93/11120
D9 WO 95/03795

III. Notice of opposition was filed by the appellant, requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty, lack of inventive step, insufficiency of disclosure and added subject-matter (Article 100(a), (b) and (c) EPC).

IV. The decision under appeal is based on the patent as granted (main request) and a set of claims consisting of a single claim according to auxiliary request 1 filed on 29 November 2012 at the oral proceedings before the opposition division (former auxiliary request 3 filed by letter dated 26 September 2012).

The opposition division decided that the subject-matter of claim 1 as granted extended beyond the content of the application as filed, contrary to the requirement of Article 100(c) EPC. The subject-matter of the sole claim according to auxiliary request 1 was considered to comply with the requirements of Articles 123(2) and 84 EPC. Its subject-matter was sufficiently disclosed and novel and inventive over the prior art.

The sole claim of auxiliary request 1, which the opposition division considered to meet the requirements of the EPC, reads as follows:

"1. Use of a cytostatic therapeutic agent for the preparation of a medicament for inhibiting one or more pathological activities of normal mammalian vascular smooth muscle cells for a period of time sufficient to maintain an expanded vessel luminal area, wherein the cytostatic therapeutic agent is the cytoskeletal inhibitor taxol and wherein the therapeutic agent is administered directly or indirectly to a traumatized vessel."

V. With the statement of grounds of appeal, the appellant maintained its objections of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step. It also raised additional objections of non-compliance with Article 123(3) EPC, invalidity of priority, lack of clarity and lack of novelty over the disclosure of document D9 filed with the statement of grounds of appeal.

VI. With the reply to the statement of grounds of appeal, the respondent defended the patent in suit on the basis of auxiliary request 1 on which the decision under appeal was based (hereinafter: "main request"), and filed sets of claims according to first and second auxiliary requests.

The sole claim of the first auxiliary request reads as follows:

1. Use of a cytostatic therapeutic agent capable of inhibiting one or more pathological activities of vascular smooth muscle cells, said cytostatic

therapeutic agent being the cytoskeletal inhibitor taxol, for the preparation of a medicament for inhibiting one or more pathological activities of normal mammalian vascular smooth muscle cells for a period of time sufficient to maintain an expanded vessel luminal area, wherein said therapeutic agent is administered to a mammal in an effective amount and wherein said therapeutic agent is administered directly or indirectly to a traumatized vessel.

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the expression "or indirectly" has been deleted.

VII. By letter of 23 July 2015, the respondent filed additional sets of claims according to auxiliary requests 1A and 2A. These requests were subsequently withdrawn (see point XIV below).

VIII. In a communication dated 16 March 2018, the board informed the parties that the patent had expired 20 years after the filing date and that the appeal proceedings would be discontinued unless a request for continuation was filed within two months from the notification of that communication (Rule 84(1) in conjunction with Rule 100(1) EPC) or the state of the file gave the board grounds to continue the proceedings of its own motion.

IX. By letter of 7 May 2018, the appellant requested that the appeal proceedings be continued.

X. The board issued summons to oral proceedings.

XI. In reply, the respondent withdrew its request for oral proceedings and informed the board that it would not be

attending the oral proceedings scheduled for 19 December 2019. The respondent stated that it maintained the request for the patent in suit to be maintained in amended form according to auxiliary request 1 on which the decision under appeal was based.

XII. In a communication dated 14 November 2019, the board requested the respondent to clarify whether it maintained its auxiliary requests filed with the statement of grounds of appeal (i.e. the first and second auxiliary requests) and by letter dated 23 July 2015 (i.e. auxiliary requests 1A and 2A). In addition, the board indicated that the understanding and clarity of claim 1 of the main request were considered to be relevant for the examination of novelty and added subject-matter and would be discussed at the oral proceedings. The board gave its preliminary opinion on this issue, indicating *inter alia* that the expression "wherein the therapeutic agent is directly and indirectly administered" could be understood in different ways.

XIII. By letter of 25 November 2019, the appellant informed the board that it was withdrawing its request for oral proceedings and that it would not be attending the oral proceedings on 19 December 2019.

XIV. By letter of 3 December 2019, the respondent withdrew auxiliary requests 1A and 2A. No observations or comments as regards the board's preliminary opinion were provided.

XV. The appellant's arguments, as far as they concern the decisive issues of the present decision, can be summarised as follows:

The feature "direct or indirect administration" was not defined in the application as filed. The opposition division's finding that the person skilled in the art would be aware of direct (stent) and indirect (injection) routes of administration could not be accepted because - according to the opposition division - the subject-matter had never been disclosed in the prior art.

The application as filed referred to direct and targeted delivery. Therefore, the expression "direct and indirect" seemed to be an alternative wording for "direct and targeted". Administration of conjugates from which taxol could be released could be regarded as indirect administration of taxol. The use of such conjugates was even a preferred embodiment in the application as filed. The wording of the claim did not exclude the possibility of taxol being used for preparing a conjugate which was then included in a medicament.

XVI. The respondent's arguments, as far as they concern the decisive issues of the present decision, can be summarised as follows:

The term "direct or indirect administration" was clear to the person skilled in the art. The term "administration" was commonly understood in the art as referring to the path by which a drug formulation is taken into the body (i.e. by mouth, by injection, by inhalation, via rectum, by topical application, etc.). It was therefore evident to the skilled person that claim 1 of the main request defined the route of administration by which the drug, in its final form to be dispensed by the physician, was supposed to be delivered to the vessel. Claim 1 of the main request

required taxol to be delivered to the vessel. If taxol were assumed to be released only after cleavage from a conjugate in the target vessel, this would mean that a taxol conjugate was actually administered, which contradicted the wording of claim 1 of the main request.

The term "direct or indirect administration" to a vessel was therefore perfectly clear to the skilled person. Direct administration referred to the administration of the drug directly into the vessel (e.g. by catheter or stent). Indirect administration involved another body medium as an intermediate carrier, for instance injection of a taxol solution into the bloodstream in the vicinity upstream of the vessel to be treated.

XVII. The appellant requested in writing that the decision under appeal be set aside and the patent be revoked.

XVIII. The respondent requested in writing

- that the appeal be dismissed;
- that, if document D9 were considered to be relevant to patentability and/or document D2 were considered to be relevant for inventive step, the case be remitted to the opposition division; or
- alternatively, that the patent be maintained on the basis of the set of claims of the first or the second auxiliary request, submitted with the reply to the statement of grounds of appeal.

XIX. At the end of the oral proceedings, which took place as scheduled on 19 December 2019, the board's decision was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Non-appearance of a party at oral proceedings before the board

2.1 Neither the appellant nor the respondent attended the oral proceedings before the board, to which they had been duly summoned (see points XI and XIII above).

2.2 According to Rule 115(2) EPC, oral proceedings may continue in the absence of any duly summoned party that does not appear. According to Article 15(3) RPBA 2007, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned, who may then be treated as relying only on its written case. In deciding not to attend oral proceedings, the appellant and the respondent chose not to avail themselves of the opportunity to present their observations and comments orally.

2.3 The present decision is based on the grounds, facts and evidence put forward during the written proceedings, on which the parties had the opportunity to present their observations and comments. The board was therefore in a position to take a final decision at the oral proceedings, despite the absence of the duly summoned parties.

Main request

3. Clarity (Article 84 EPC)

3.1 The sole claim of the main request is directed to the use of taxol for the preparation of a medicament for inhibiting one or more pathological activities of normal mammalian vascular smooth muscle cells for a sufficient period of time to maintain an expanded vessel luminal area. Taxol is identified as a cytoskeletal inhibitor and characterised as a cytostatic therapeutic agent. It is administered directly or indirectly to a traumatised vessel.

According to the appellant, the claim's basis is found in claims 1 and 3 and on page 25, line 32 to page 27, line 24 of the application as filed. The board notes that the sole claim of the main request is not the result of a combination of claims as granted and that some features, such as the inhibition of one or more pathological activities or the direct and indirect administration, were not present in the claims as granted. In such a case, according to established case law of the boards of appeal, the opposition division and the board have the power under Article 101(3) EPC to examine whether the amendments introduce any contravention of requirements of the EPC, including Article 84 EPC (G 3/14). This was not disputed.

3.2 Under Article 84 EPC in combination with Rule 43(1) EPC, the claims must be clear and define the matter for which protection is sought in terms of the technical features of the invention. These requirements are there to ensure that the public is not left in any doubt as to what subject-matter is covered and not covered by a claim. Accordingly, a claim cannot be considered clear within the meaning of Article 84 EPC if it does not unambiguously allow this distinction to be made. A claim comprising an unclear or ambiguous technical feature therefore entails doubts as to the subject-

matter covered by that claim. This applies all the more if the unclear feature is essential with respect to the invention in the sense that it is intended to delimit the subject-matter claimed from the prior art, thereby giving rise to uncertainty as to whether or not the subject-matter claimed is anticipated (see decision T 560/09, not published, point 2 of the reasons).

3.3 In the case in hand, feature iii) requires the therapeutic agent to be directly or indirectly administered to a traumatised vessel. According to the opposition division and the respondent, the person skilled in the art would construe this feature as clearly referring to the administration of taxol *per se* to either the point in the vessel where the trauma occurred (direct administration), for example via a stent or an infusion catheter, or a different point from that where the trauma occurred (indirect administration), for example via injection. In the opposition division's and the respondent's view, taxol conjugates, as disclosed in document D2, were therefore clearly excluded from the scope of claim 1 of the main request.

3.4 However, the opposition division's and the respondent's interpretation is not the only way of construing the aforementioned feature. In the board's view, another equally valid and technically feasible understanding of feature iii) is the administration of the therapeutic agent either *per se* (direct administration) or in a form from which it can be released (indirect administration), such as a conjugate, in which case conjugates would not be excluded from the scope of the claim. It should be noted that the term "indirect administration" was not defined in the application as filed, which drew a distinction between targeted and

direct delivery. It is therefore not unreasonable to assume that the expression "indirect administration" was meant to reflect the targeted delivery of the therapeutic agent, as argued by the appellant.

The board therefore does not accept the respondent's arguments that the wording of claim 1 required taxol *per se* to be administered and that it then followed that feature iii) clearly referred to the point of delivery (see point XVI above). Claim 1 is not directed to a particular final dosage form which is administered to the vessel and which contains the therapeutic agent in a particular, i.e. free, form.

3.5 It follows from the above that feature iii) is not only broad, as argued by the opposition division, but also ambiguous as it can be understood in various ways, i.e. as referring to the point of delivery of the therapeutic agent or to the form in which the therapeutic agent is delivered. This leaves the public in doubt as to what subject-matter is covered and not covered by claim 1 of the main request.

Hence, the board concludes that claim 1 of the main request is not clear within the meaning of Article 84 EPC. The main request is therefore not allowable.

Auxiliary requests

4. Clarity (Article 84 EPC)

4.1 Claim 1 of the first auxiliary request differs from claim 1 of the main request essentially in that the cytostatic therapeutic agent to be used, i.e. taxol, is further characterised as being capable of inhibiting one or more pathological activities of vascular smooth

muscle cells and in that it is administered to a mammal in an effective amount (see point VI above).

4.2 Claim 1 includes the same feature iii) as used in claim 1 of the main request. Consequently, the considerations regarding clarity set out in point 3 apply, *mutatis mutandis*.

4.3 The board therefore concludes that the first auxiliary request is not allowable for non-compliance with Article 84 EPC.

4.4 Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that it is limited to direct administration of the therapeutic agent (see point VI above).

4.5 This does not change the board's assessment regarding the clarity of the claimed subject-matter. It is still unclear whether the expression "direct administration" refers to the point of delivery or to the form in which taxol is delivered.

4.6 Hence, the board concludes that the second auxiliary request contravenes Article 84 EPC and is therefore also unallowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated