

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 24 February 2021**

Case Number: T 2010/18 - 3.3.04

Application Number: 12811843.7

Publication Number: 2731619

IPC: A61K38/42, A61K47/48,
A61K47/30, A61P35/00

Language of the proceedings: EN

Title of invention:

A heat stable oxygen carrier-containing pharmaceutical composition for different treatment applications

Applicant:

Billion King International Limited

Headword:

Oxygen carrier containing pharmaceutical/BILLION KING

Relevant legal provisions:

EPC Art. 54, 84, 123(2)

RPBA 2020 Art. 15(8)

RPBA Art. 12(4)

Keyword:

Main request and auxiliary request 1 - added subject-matter and lack of clarity (yes)

Auxiliary requests 2 and 3 - admitted into proceedings (no)

Auxiliary requests 4,5,7,8 - novelty (no)

Auxiliary request 6 - added subject matter (yes)

Abridged reasons for decision

Decisions cited:

Catchword:

-



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2010/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 24 February 2021

Appellant: Billion King International Limited
(Applicant) Room 2301, 23rd Floor, Fu Fai Commercial Centre
27 Hillier Street
Sheung Wan
Hong Kong (HK)

Representative: Modiano, Micaela Nadia
Modiano & Partners
Thierschstrasse 11
80538 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 9 March 2018
refusing European patent application No.
12811843.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair G. Alt
Members: B. Claes
P. de Heij

Summary of Facts and Submissions

- I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse European patent application No. 12 811 843.7, published as international patent application WO 2013/009790, entitled "*A heat stable oxygen carrier-containing pharmaceutical composition for different treatment applications*".
- II. The examining division decided that claim 1 of each claim request contained added subject-matter (Article 123(2) EPC), and that the subject-matter of claims 1 to 4 of the main request and of auxiliary requests 1, 4 and 5 failed to meet the requirements of Articles 54(1), (2) and 87(1) EPC. The finding on novelty also applied to claims 1 to 3 of auxiliary request 2.

Claim 1 of the main request dealt with in the decision under appeal read:

"1. A non-polymeric, highly purified and heat stable oxygen carrier containing composition comprising a cross-linked tetrameric hemoglobin with an undetectable dimer concentration *for use to prevent post-operative liver tumor recurrence and metastasis following hepatic resection in a mammal, wherein said composition is administered to said mammal prior to disruption of blood supply, increasing oxygenation after introduction of ischemia and during re-establishment of blood supply during the hepatic resection.*" (emphasis added by the board)

III. With its statement of grounds of appeal, the appellant filed a new main request and new auxiliary requests 1 to 3. Former auxiliary requests 1 to 5 were re-submitted as auxiliary requests 4 to 8. The appellant filed arguments that the claims of these requests complied with the requirements of Articles 54, 56 and 123(2) EPC.

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the claims of the new main request or, alternatively, on the basis of the claims of one of auxiliary requests 1 to 8. Oral proceedings were requested on an auxiliary basis.

Claim 1 of the (new) main request read:

"1. A non-polymeric, highly purified and heat stable oxygen carrier containing composition comprising a cross-linked tetrameric hemoglobin with an undetectable dimer concentration *for use in administration prior to disruption of blood supply and during re-establishment of blood supply during a surgical removal of a tumor, reducing cancerous tumor recurrence and/or minimizing tumor cell metastasis in a mammal and reducing size of a recurrent tumor.*" (emphasis added by the board)

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request except for the qualification that the "tumor" is a "hepatic tumor".

Claims 1 of auxiliary requests 2 to 8 are identical to claim 1 of the main request except that the wording starting with the word "for" (see word emphasised by the board) has been replaced by the following respective wordings:

Auxiliary request 2: "for reducing cancerous tumor recurrence and/or minimizing tumor cell metastasis in a mammal, wherein said composition is administered prior to disruption of blood supply and during re-establishment of blood supply during a surgical removal of a hepatic tumor, to bring about increased oxygenation after introduction of ischemia, compared to non-treatment."

Auxiliary request 3: "for use to reduce circulating endothelial progenitor cell levels following tumor resection in a mammal suffering from cancer, by administering said composition prior to disruption of blood supply and during re-establishment of blood supply during surgical removal of a tumor."

Auxiliary request 4: "for use to decrease circulating endothelial progenitor cell levels following hepatic resection in a mammal, wherein said composition is administered to said mammal prior to disruption of blood supply, and during re-establishment of blood supply during hepatic resection."

Auxiliary request 5: "for use to prevent post-operative liver tumor recurrence and metastasis following hepatic resection in a mammal, wherein said composition is administered to said mammal at 0.2-0.4g/kg body weight prior to disruption of blood supply, increasing oxygenation after introduction of ischemia and during re-establishment of blood supply during the hepatic resection, yielding an approximately 3-fold higher partial oxygen pressure after reperfusion."

Auxiliary request 6: "for use to prevent post-operative liver tumor recurrence and metastasis following hepatic

resection in a mammal, wherein said composition is administered to said mammal approximately 35 minutes prior to disruption of blood supply and during re-establishment of blood supply during the hepatic resection."

Auxiliary request 7: "for use to prevent post-operative liver tumor recurrence and metastasis following hepatic resection in a mammal, wherein said composition is administered to said mammal prior to disruption of blood supply, and during re-establishment of blood supply during hepatic resection, decreasing circulating endothelial progenitor cells levels at 7, 14, 21 and 28 days post-surgery."

Auxiliary request 8: "for use to decrease circulating endothelial progenitor cell levels following hepatic resection in a mammal, wherein said composition is administered to said mammal one hour prior to disruption of blood supply, and during re-establishment of blood supply during hepatic resection."

- IV. In a communication pursuant to Rule 100(2) EPC which accompanied the summons to oral proceedings, the board informed the appellant of its preliminary opinion that: claim 1 of the main request and of auxiliary request 1 lacked clarity and contained added subject-matter; the subject-matter of claim 1 of the main request and of auxiliary requests 1, 4, 5, 7 and 8 lacked novelty over the disclosure in document D2 (WO 2011/162863) and/or D3 (US 7 932 356 B1); and that claim 1 of auxiliary request 6 contained added subject-matter; it also informed the appellant of its intention not to admit auxiliary requests 2 and 3 into the proceedings.

- V. The appellant duly responded to the communication. The reply was confined to the statement: "*The request for oral proceedings is withdrawn. A decision based on the state of the file is requested.*" The appellant did not submit further substantive facts or arguments.

Reasons for the Decision

1. The appeal is admissible.
2. Since the request for oral proceedings had been withdrawn, the board came to its decision in written proceedings.

*Main request and auxiliary request 1 - claim 1
Clarity (Article 84 EPC) and added subject-matter
(Article 123(2) EPC)*

3. The technical effect resulting from the administration in accordance with the claim is "reducing cancerous tumor recurrence and/or minimizing tumor cell metastasis in a mammal and reducing size of a recurrent tumor". This feature can be parted as "i) reducing cancerous tumor recurrence in a mammal and/or ii) minimizing tumor cell metastasis in a mammal and iii) reducing size of a recurrent tumor", i.e. "i) and/or ii) and iii)".
4. It is unclear from this wording whether sub-feature iii) is to be read in combination with sub-feature i) and/or ii) (i.e. implying that the effect of reducing size of a recurrent tumor is in any case required) or just with ii) (i.e. implying that the effect is optional). In its broadest interpretation, therefore,

the feature covers at least each of the following combinations:

- a) i) + iii);
- b) ii) + iii); and
- c) i) + ii) + iii).

5. In the context of sub-feature iii), the appellant referred to paragraphs [0017] and [0142] of the application as filed as allegedly providing a basis. However, paragraph [0142] of the application logically links sub-feature i) to sub-feature iii) ("*where tumor recurrence is seen, the sizes of the recurred tumors ... are significantly smaller than those untreated*"). Furthermore - although possibly a basis is disclosed for sub-features i) + iii) and/or ii) in the context of hepatic cancer - neither paragraph provides a basis for possibility b) above. In addition, whereas paragraph [0142] reads on a passive interpretation of the sub-feature "reducing size of a recurrent tumor" ("*the sizes of the recurred tumors ... are significantly smaller*", i.e. the growth is inhibited resulting in smaller tumors), in the context of the claim this sub-feature can be interpreted either passively or actively (i.e. not reducing the growth of recurring tumors but rather reducing the size of a recurred tumor). Obviously, however, this latter interpretation is not disclosed in paragraph [0142].
6. Consequently, the board holds the feature "reducing cancerous tumor recurrence and/or minimizing tumor cell metastasis in a mammal and reducing size of a recurrent tumor" to lack clarity (Article 84 EPC) and in addition to constitute added subject-matter (Article 123(2) EPC).

Auxiliary requests 2 and 3

Admittance into the proceedings (Article 12(4) RPBA 2007)

7. As compared with claim 1 of the main request dealt with by the examining division (see section II), which was aimed at the technical effect "to prevent [...] liver tumor recurrence and metastasis", claim 1 of auxiliary request 2 (see section IV) is now aimed at the technical effect of "reducing cancerous tumor recurrence and/or minimizing tumor cell metastasis".
8. As compared with claim 1 of auxiliary request 1 dealt with by the examining division (see section III, auxiliary request 4), claim 1 of auxiliary request 3 (see section III) now - rather than relating to *hepatic* tumor resection - relates more generally to tumor resection.
9. The appellant has not submitted any arguments as to why these two auxiliary requests could not have been presented in the examination proceedings (Article 12(4) RPBA 2007). The board equally has difficulties in identifying good reasons for this.
10. The appellant has furthermore not explained why and to what extent the amended claims constitute a *bona fide* reaction to the findings in the decision under appeal. Indeed, the board has seen no arguments from the appellant, and it is also not clear to the board, how a broadening of the claimed subject-matter ("and" replaced by "and/or" and "liver resection" replaced by "tumor resection") can overcome objections to e.g. novelty as formulated by the examining division in relation to claim 1 of the main request and auxiliary request 1, respectively.

11. As concerns claim 1 of auxiliary request 3, nor has the board seen arguments from the appellant which address the decision of the examining division that claim 1 of auxiliary request 1 present before it was not in the format of a further medical use claim.
12. In view of these considerations, the board decided not to admit auxiliary requests 2 and 3 into the proceedings (Article 12(4) RPBA 2007).

*Auxiliary requests 4, 5, 7 and 8
Novelty (Article 54 EPC)*

13. In its communication (see section IV), the board informed the appellant that it was not convinced by the arguments which it had submitted in the statement of grounds of appeal in the context of novelty. In fact, the arguments relied on by the appellant had already been submitted (see letter dated 2 January 2018, section "Novelty (Article 54 EPC)" to, and considered by, the examining division in the decision under appeal. As noted in its communication, the board's preliminary view concurred with the examining division's reasoning that the subject-matter of claim 1 of auxiliary requests 1, 2, 4 and 5 - (numbered auxiliary requests 4, 5, 7 and 8 in these appeal proceedings) lacked novelty over the disclosure in document D2 and/or document D3 (see decision under appeal, points 32 to 37, 42 to 45, 56 to 59 and 63 to 62).
14. The above-mentioned preliminary finding of the board has not subsequently been commented on nor contested by the appellant (see section VI). Under these circumstances, the board - having taken into consideration all the relevant aspects concerning

novelty - sees no reason to deviate from its preliminary finding.

15. As a consequence, the board fully agrees with the examining division's findings in this context, to which reference is made above, which are adopted by the board (Article 15(8) RPBA 2020).

Auxiliary request 6 - claim 1

Added subject-matter (Article 123(2) EPC)

16. In the statement of grounds of appeal, the appellant merely pointed "*to the reasons as given already before the first instance*" (see page 12, point 3.g., second paragraph) without setting out why the decision under appeal was wrong to consider claim 1 to contain added subject-matter. In its communication (see section V), the board informed the appellant that it agreed with the examining division that Figure 21 of the application as filed failed to disclose to the skilled person the particular features of claim 1 of auxiliary request 6 (previously auxiliary request 3) and that the claim therefore, as the examining division held (see decision under appeal, points 48 to 51), contained added subject-matter.
17. This preliminary finding of the board has not subsequently been commented on nor contested by the appellant either (see section VI). Here too, the board sees no reason to deviate from its preliminary finding.
18. As a consequence, here too the board fully agrees with the examining division's findings in this context, to which reference is made above, which are adopted by the board (Article 15(8) RPBA 2020).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

G. Alt

Decision electronically authenticated